CHAPTER 3

ADDITIONAL PROGRAM ACTIVITIES

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Adverse Actions

Section

## Adverse Actions



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## 3000. ADVERSE ACTIONS - GENERAL

A. Applicability.--The Regional Office (RO) and State survey agency (SA) follow the procedures in this part if an adverse action is likely to be initiated against Medicare participating providers and suppliers. Because many Medicare providers also participate in the Medicaid program and Federal procedures must also be followed when surveying and certifying providers that only participate in the Medicaid program, these procedures generally apply to both programs. Exceptions for Medicaid are noted.

For Medicaid-only facilities, termination procedures are not State plan requirements. However, a State risks disallowance of Federal matching funds for failure to use Federal standards and the forms, methods, and procedures prescribed by HCFA. (See 42 CFR 442.30.)

B. State Ombudsman Programs.--To coordinate with the State ombudsman network, the SA should establish procedures to:

- Notify the State ombudsman of decisions to initiate proceedings to terminate, or nonrenew a provider agreement;

- Notify the State ombudsman of voluntary terminations and planned terminations, including dates of closure;

- Consider ombudsman information about situations in the facility and the credibility of the provider's allegations of compliance; and

- Share statements of deficiencies and Plans of Correction (PoCs).

C. HCFA Authority to Terminate Medicare and Medicaid Participation.--

1. Noncompliance with Conditions of Participation (CoPs), Conditions for Coverage, or Requirements for SNFs.--The RO is delegated authority to terminate Medicare participation of all providers and suppliers because of noncompliance with the applicable regulatory requirements, or Conditions of Participation or Coverage.

2. Violations of Provider Agreements, Peer Review Organization (PRO) Sanctions, or Program Abuse.--The Secretary's authority to terminate provider agreements is delegated to the Associate Regional Administrator and may be redelegated to the Branch Chief, but other components may be authorized to find that termination is in order. Accordingly, the RO handles terminations on grounds other than noncompliance with the CoPs in accordance with §3032.

3. "Look Behind" Cancellation of Medicaid Intermediate Care Facility/Mentally Retarded (ICF/MR) Agreements.--The ROs are authorized to cancel the approval of an ICF/MR to participate in the Medicaid program when the ICF/MR fails to comply substantially with regulatory CoPs. (See §1910(b) of the Act.)

4. Termination of Nursing Facility (NF) Medicaid Agreements.--The ROs are, under certain circumstances, authorized to terminate a NFs participation in the Medicaid program. (See §1919(h) of the Act and Chapter 7 of the SOM.)

## 3001. INITIAL DENIALS OF MEDICARE PROVIDER/SUPPLIER REQUESTS FOR PROGRAM PARTICIPATION

Denials are made only when there has been an expression, written or otherwise, of interest in participating (or in expanding the scope of existing participation) and/or an initial survey is

performed. Because the RO makes the compliance decision for Medicare, The SA should not lead the provider/supplier to believe that it has been approved and can start to furnish services to Medicare beneficiaries.

An initial denial is made when, after evaluating the evidence the adjudicating office (in this case the RO) finds that the requirements of law and regulation are not met. The SA forwards recommendations for initial denials to the RO within 10 days after the date of survey. Formal written denial notices which explain the right to appeal are issued by the RO as soon as possible.

A. Authority For Adjudicating Denials.--The RO adjudicates all approvals or disapprovals for Medicare participation. 42 CFR 498 addresses determination and appeal procedures. 42 CFR 488 provides the basis for denying suppliers of services. The statutory authority is implied in §§1819, 1832, 1861, and 1881 of the Act which authorize the Secretary to establish CoPs or Conditions for Coverage.

B. Vacated Actions Which Are Not Denials.--If the SA is contacted by a potential provider and it schedules a survey, but the survey is cancelled after finding that the party is either no longer interested in participating or in meeting program requirements, the SA notifies the RO by Form HCFA-1539, indicating the lack of interest. The RO sends a written notice to the potential provider to document the reason why certification action was not completed. Despite the lack of interest, if the potential provider operates a Skilled Nursing Facility (SNF), and the SA has sufficient information, the SA prepares a §1819(a)(1) (formerly §1861(j)(1)) certification, if indicated. (See §2164.)

C. Vacated Actions Which Are Denials.--If a potential provider or supplier is surveyed and deficiencies are cited, the SA forwards Form HCFA-1539 and related documentation to the RO, even when the request for participation is withdrawn. The RO either notifies the provider or supplier of the failure to meet eligibility requirements or affirms the provider's or supplier's request to withdraw. The SA uses Form HCFA-1539 to transmit all certification forms and pertinent documents to the RO within 45 days of the survey. A §1819(a)(1) certification is included, if indicated.

D. RO Processing of Denials.--The RO processes the denial and sends the provider or supplier a formal notice, with a copy to the SA, the State Medicaid Agency SMA), and the intermediary, if applicable, documenting the basis for the action.

The RO includes the following information in the formal notice:

- The date of the notice;
- The decision and reason for it (cite provisions of the law or regulations not met);
- The right to request participation in the future; and
- The procedures to follow for a formal reconsideration and a hearing before an administrative law judge (ALJ).

A denial notice must be signed by the RO official delegated to adjudicate denials.

## 3005. BASIS FOR TERMINATING PROVIDER PARTICIPATION - CITATIONS AND DISCUSSION

A. Medicare Provider Agreements.--Provider agreements and agreements with clinics as to the provision of Outpatient Physical Therapy (OPT) are terminated by the RO under the authority of §1866(b) of the Act. (See 42 CFR Part 489.52-489.57.) Medicare providers (as defined in §2002) must substantially meet each of the applicable CoPs.

B. Termination of Coverage of Supplier Services Subject To Certification. Sections 1832(a), 1861(g), (p), (s), and (aa) and 1881(b) of the Act authorize the Secretary to establish Conditions for Coverage of supplier services and thus implicitly authorize determinations that the Conditions cease to be met. 42 CFR 498.3(b) provides that the Secretary makes findings, setting forth pertinent facts and conclusions, and an initial determination as to whether a supplier meets the respective Conditions. The determination can be a result of the written request by the supplier to start or expand services or to establish that it continues to meet respective Conditions for Coverage. An adverse determination may involve one or more areas of services offered by a supplier. While these adverse determinations are not in the regulations as "terminations," their effect on payment for the supplier's services is the same as when a provider agreement is terminated. Procedures for certifying supplier noncompliance parallel those for certifying provider noncompliance.

For example, the agreement which an Ambulatory Surgical Center (ASC) or Rural Health Clinic (RHC) enters into is a specific agreement related to those suppliers, not a provider agreement.

C. Decision To Terminate or Deny Payment For Medicaid Facilities.--

1. Medicaid ICFs/MR.--If deficiencies do not present an immediate jeopardy to residents' health and safety, the SMA has the option to deny payments for new admissions under §1902(i) of the Act or invoke termination. The SMA is not required to accept the SA recommendation as to whether to terminate or deny payments for new admissions.

2. Medicare-Medicaid SNFs/NFs.--For dually-participating SNFs/NFs, the decision to deny payments for new admissions is made in accordance with §§1819(h) and 1919(h) of the Act. (See §§7506 and 7807.)

3. Other Providers.--The SMA must terminate the Medicaid agreement when the SA determines that a provider (there are no suppliers in Medicaid) other than a long-term care facility does not meet applicable program requirements. Where partial terminations are made, such as for specific CLIA laboratory tests, the Medicaid determination must follow suit.

D. Cause For Termination.--HCFA may terminate provider participation (Medicare providers only) if the provider does not comply with a CoP or Requirement of Participation (for SNFs) or fails to provide an acceptable PoC for other requirements. (See 42 CFR Part 489.53.)

Certain causes for termination are unrelated to certification and have no impact on the SA. HCFA may terminate provider participation if:

1. The provider places restrictions on the persons it accepts for treatment, and fails either to exempt Medicare beneficiaries from the restrictions, or to apply the same restrictions to Medicare beneficiaries as to all other persons seeking care;

2. The provider refuses to permit examination of its records by or on behalf of HCFA for verification of information it furnished as a basis for payment;

3. The provider has knowingly and willfully made, or caused to be made, false statements or representations of a material fact for use in a request for payment;

4. The provider has submitted, or caused to be submitted, requests for payment under Medicare, or amounts for items and services, substantially in excess of the costs incurred;

5. The provider has furnished items or services which HCFA determined to be substantially in excess of the needs of individuals or of a quality that failed to meet professionally recognized standards; or

6. The provider fails to:

- o Permit photocopying of any records necessary to determine compliance;
- o Furnish information necessary for HCFA to determine whether payments are or were due under Medicare and the amount due;
- o Furnish information on business transactions as required;
- o Disclose information on convicted principals;
- o Furnish ownership information;
- o Comply with civil rights requirements; or
- o Furnish notice of discharge rights.

7. A hospital or rural primary care hospital that has reason to believe it may have received an individual by another hospital in violation of 42 CFR 489.24 fails to report the incident.

8. A hospital fails to furnish inpatient services to CHAMPUS or CHAMPVA beneficiaries or to veterans.

9. A rural primary care hospital fails to maintain an average length of stay of 72 hours or less.

The SA determines provider compliance with certification requirements. FIs generally are responsible for dealing with matters related to payment and coverage. However, in the course of a survey, the SA may encounter information indicative of program abuse or failure to meet requirements described in the above list. The SA communicates these areas of concern to the RO.

E. Termination of Title XIX-Only NFs and ICFs/MR.--Medicaid regulations provide for terminations, and for ICFs/MR nonrenewals, and cancellations, but do not describe the implementing procedures. Each SMA has procedures for terminating agreements with NFs and ICFs/MR when they are not in substantial compliance with program requirements. In any Medicaid-only noncompliance situation, the SA initiates the action, prepare the necessary documents, and forward them to the SMA, which has responsibility for the termination, nonrenewal, or cancellation of the agreement (see §7300 for the exception regarding State operated NFs). In this case, the SMA notifies HCFA and the public of its action and affords the facility notice and opportunity for a hearing before an ALJ prior to termination.

Under 42 CFR 431.54(f), the SMA may "lock out" a Medicaid provider for a reasonable period if it has abused the Medicaid program. This may occur even though the SA has approved the facility. There are no certification instructions directing the SA to participate in "lock out" procedures.

F. Termination Action Based Upon Onsite Federal or Validation Survey of an Accredited Entity.--When immediate and serious threat to patient health and safety is found, whether in the course of a scheduled Federal monitoring survey, in response to a complaint, or as part of sample validation efforts of an accredited entity, the RO initiates termination procedures. Survey findings and factual development are the responsibility of the RO. However, the SA may be asked to assist in documenting or developing aspects of the termination. The SA (and the SMA, if the provider/supplier also participates in Medicaid) is notified by the RO of the action taken.

G. Look Behind Authority of HCFA

1. "Look-Behind" Termination or Cancellation of ICF/MR Agreement by the Secretary.--HCFA has authority under §1910(b) of the Act to terminate approval of an ICF/MR to participate in the Medicaid program when it determines that the facility fails to comply substantially with the CoPs, 42 CFR Part 483, Subpart I, or to submit an acceptable PoC.

The cancellation is prospective, usually after the provider has had the opportunity for a formal hearing before an ALJ.

If there is no immediate and serious threat to resident health and safety and HCFA elects to terminate, the ICF/MR is afforded an opportunity for a pre-termination hearing before an ALJ. If the effective date of termination is held in abeyance pending an ALJ's ruling and the ICF/MR makes a credible allegation of compliance while the hearing is pending, it is up to the RO to determine whether it is in the recipients' and the government's interest to resurvey the facility and dispose of the case based on the findings. If a revisit is made and the ICF/MR failed to achieve compliance, adverse action continues based on the findings of the first Federal survey and the revisit. If the ALJ affirms the HCFA decision, the effective date of termination is set by the ALJ.

If there is an immediate and serious threat to resident health and safety, HCFA terminates or cancels approval of the ICF/MR and affords it the opportunity for a post-termination ALJ hearing.

Following termination, ICFs/MR wanting readmission must request a survey from the RO. The RO directs the SA to do a survey unless it feels that a Federal survey is necessary. HCFA must be satisfied that the reasonable assurance provision is met before the State executes a Medicaid agreement with the ICF/MR.

2. Old "Look-Behind" Termination of a NF or ICF/MR by the Secretary.--Under 42 CFR 442.30, a provider agreement of a SNF, NF, or ICF/MR is considered invalid for purposes of providing FFP to the State unless the State has followed proper survey and certification procedures. For example, the SMA may have issued the provider agreement even though it had not certified the facility as being in compliance. Other examples of procedural error include, but are not limited to:

- The SA fails to use TLAs or automatic cancellation clauses when required (ICFs/MR);
- The SA fails to request an extension of the agreement from the SMA before the agreement expires (ICFs/MR);
- The SA documents noncompliance yet certifies compliance;
- The SA certifies compliance, but all cited deficiencies are not covered by an acceptable PoC;
- The SA fails to survey against all applicable requirements; or
- The SA fails to use Federally approved survey and certification documents.

When procedures are not followed by either the SA or SMA, HCFA considers the provider agreement void from its inception, and the State is disallowed FFP for bills related to the facility for the period covered by that Medicaid agreement. This type of adverse action, referred to as "Old Look Behind," is covered in more detail in §3042.

3. SMA Disagrees with SA Determination.--With the exception of State-operated NFs, the SA surveys and certifies compliance of Medicaid facilities with health and safety requirements to the SMA. The SMA is responsible for reviewing certifications to ensure that the SA has adhered to procedural requirements. If the SMA disagrees with the SA's certification, it first contacts the SA to resolve the issue. If the issue cannot be resolved, it contacts you. To resolve the dispute, conduct a Federal survey of the facility or take other action as necessary.

## 3005.1 DENIAL OR TERMINATION BASED UPON FAILURE TO DISCLOSE OWNERSHIP AND CONTROL INTEREST

If a denial or termination is based on failure to complete Form HCFA-1513 to disclose ownership and control interest information, the SA forwards any pertinent correspondence to the RO and the RO denies or terminates in accordance with CFR Part 489.53(8).

## 3006. DENIAL OF PAYMENTS IN LIEU OF TERMINATION OF ICFs/MR

A. Authority To Deny Payment For Any New Admissions For ICFs/MR.--Section 1902(i) of the Act and 42 CFR 442.118 provide the SMA with an alternative to terminating ICFs/MR that fail to meet program requirements. This sanction is the one-time denial of payment for new admissions for a period of up to 11 months after the month it was imposed, if the facility's deficiencies do not present an immediate jeopardy to residents' health and safety. A decision is made at the end of 11 months whether to continue participation. However, the 11-month period can be shortened if circumstances change and there is immediate jeopardy to health and safety before 11 months have passed. Alternatively, the State might rescind the denial of payments in fewer than 11 months if full compliance is achieved or if the ICF/MR has made significant, good-faith efforts and progress in achieving compliance.

B. Criteria For Imposing Denial of Payments For New Admissions.--The SMA retains the right to establish its own criteria for imposing this sanction. However, the SMA may not use this sanction if the facility's deficiencies pose immediate jeopardy to the health and safety of its clients.

C. Agency Procedures.--Before denying payment for new admissions, the SMA must comply with the following requirements:

- Provide the ICF/MR up to 60 days to correct the cited deficiencies and comply with the CoP.

- If at the end of the specified period the ICF/MR has not achieved compliance, give the facility notice of intent to deny admissions and the opportunity for an informal hearing.

- If the ICF/MR requests a hearing and the decision of the hearing is to deny payment, the SMA must provide the facility and the public, at least 15 days before the effective date of the sanction, a notice that includes the effective date of the sanction and the reasons for the denial of payment.

D. Effect of Sanction on Status of Clients Admitted, Discharged, or on Temporary Leave and Readmitted Before or After Effective Date of Denial of Payment.--The client's status on the effective date of the denial of payment is the controlling factor in determining whether readmitted clients are subject to the denial of payment. Guidelines are as follows:

- Clients who were admitted and discharged before the effective date of the denial of payment are considered new admissions if they are readmitted on or after the effective date. Therefore, they are subject to the denial of payment;

o Clients admitted on or after the effective date of the denial of payment are considered new admissions. If readmitted after being discharged, they continue to be considered new admissions, and are subject to the denial of payment;

o Clients admitted before and discharged on or after the effective date of the denial of payment are considered new admissions if subsequently readmitted. Therefore, they are subject to the denial of payment;

o Clients admitted before the effective date of the denial of payment who take temporary leave before, on, or after the effective date of the denial of payment are not considered new admissions upon return and therefore, are not subject to the denial of payment; and

o Clients admitted on or after the effective date of the denial of payment who take temporary leave are not considered new admissions, but continue to be subject to the denial of payment.

NOTE: The term "temporary leave" refers to clients who leave temporarily for any reason. If clients were not subject to a denial of payment when they went on temporary leave, the term indicates that upon return they are not considered new admissions for the purposes of the denial of payment. Therefore, the term "temporary leave" is used to justify a resumption of any interrupted payment upon re-entry into the facility.

The term "leave of absence" is defined as any situation where the client is absent, but not discharged, for reasons other than admission to a hospital, SNF or NF, or distinct part of a SNF or NF. The term "leave of absence" is used for the purpose of preventing duplicate payments during an absence by assuring that the absence is not due to a temporary alternate inpatient arrangement. If the client is not on a leave of absence but is actually temporarily in an alternate inpatient situation, any ongoing payment to the facility will be interrupted as mentioned above.

The client who is not subject to the denial of payment sanction and who goes on temporary leave, whether there is a leave of absence, will not be considered a new admission for the purposes of the denial of payment sanction, upon his/her return to the facility. Any interrupted payment will be resumed. In either situation, it is expected that the client will return to the facility following leave.

E. Status of Time Limited Agreement During Denials of Payments.--To afford sufficient time to renew an agreement, the SA surveys ICFs/MR approximately 3 months before scheduled expiration of the agreement. To prevent the agreement from expiring before development is completed, the SMA, as appropriate, can extend the agreement for a single period of up to 2 months (42 CFR 442.16) provided there is no immediate jeopardy to residents' health and safety. As long as the agreement did not lapse on or before the effective date of denial of payments, the denial of payments automatically extends the life of the agreement for up to 11 full additional months following the month in which the denial of payments became effective. The agreement can only be renewed when the denial of payments expires or is rescinded.

If a change of ownership occurs during the extension period, the agreement will be assigned to the successor owner who cannot get another agreement unless the facility is in compliance. The new owner's agreement goes into effect when the facility is found in compliance.

F. Duration of Denial of Payment and Subsequent Termination of an ICF/MR.--The denial of payment for new admissions will continue for 11 months unless, before the end of that period, the SMA finds that the ICF/MR has corrected the deficiencies or is making a good faith effort to achieve compliance with the CoPs or the deficiencies are such that it is necessary to terminate the facility.

The SMA must terminate the facility's provider agreement:

- Upon finding that the ICF/MR has been unable to achieve compliance with the CoPs during the 11-month period that payments were denied for new admissions; and

- Termination is effective the day following the last day of the denial of payment period.

3006.1 Sanctions for ICFs-MR--for Non-Immediate Jeopardy.--

A. General.--The Balanced Budget Act (BBA) of 1997 provided the statutory authority for States to establish and impose sanctions that are additional to the already existing alternative sanction of denial of payment for new admissions, and which are alternative to termination in cases where the ICF/MR's deficiencies are not determined to pose immediate jeopardy to client health and safety. This strategy recognizes that deficiencies take on greater or lesser significance depending on the specific circumstances and client outcomes in each facility, and that additional enforcement options should be available so that the enforcement consequence to the facility is effective, proportionate, and appropriate to the specifics of the noncompliance.

B. Introduction.--Section 1902(i)(1)(B) of the Social Security Act (the Act), as revised by the BBA of 1997, provides that the State may establish alternative sanctions to use as enforcement remedies for deficiencies that do not constitute immediate jeopardy to client health and safety if the State can demonstrate to HCFA's satisfaction that its alternative sanctions are effective in deterring noncompliance and correcting deficiencies (see §3006.6). One or more alternative sanctions may be imposed against private or State operated ICFs/MR instead of provider agreement termination, and may also be imposed instead of or in addition to the existing alternative sanction of denial of payment for new admissions. Examples of sanctions that may be appropriate as alternative sanctions are listed in subsection C.

C. Examples of Alternative Sanctions.--States should consider establishing the following alternative sanctions in their State plan for noncompliant ICFs/MR having non-immediate jeopardy deficiencies:

- Directed plan of correction;

- Directed in-service training; and

- State monitoring.

States are not limited to establishing and using these alternative sanctions and may submit others for HCFA's approval. When the State wants to use alternative sanctions, it must be authorized to do so under its State plan by HCFA (see §3006.6). In order to be approved, the State must provide specified information to indicate that the alternative sanction and its application is not inconsistent with applicable statutory and regulatory requirements, as well as demonstrate to HCFA's satisfaction that the alternative sanction is effective in deterring noncompliance and correcting deficiencies. Many States already have experience in imposing the three intermediate sanctions specified above against nursing homes (SNF/NFs) that fail to meet participation requirements. States also have experience in imposing remedies under their State licensure authority and may also wish to submit any of those to HCFA for approval as alternative remedies for ICF/MR. While we want States to have the three specified intermediate sanctions listed above available for ICF/MR enforcement purposes, States are free to submit others for HCFA approval as well.

D. Alternatives to Termination in Non-immediate Jeopardy Situations.--When the facility is found to have deficiencies that do not immediately jeopardize the health and safety of individuals served, the State may, in lieu of terminating the facility's provider agreement:

1. Deny payment for all new Medicaid admissions to the facility after the effective date of the sanction;

2. Impose one or more of the alternative sanctions that HCFA has approved; or

3. Do both (1) and (2) above. Deny payment for all new Medicaid admissions to the facility after the effective date of the sanction and impose one or more of the alternative sanctions that HCFA has approved.

3006.2 Directed Plan of Correction (DPoC).--

A. Purpose.--A DPoC is a plan which the State develops to require an ICF-MR to take action within specified time frames. The purpose of the DPoC is to achieve correction and continued compliance with Conditions of Participation.

A DPoC differs from a traditional plan of correction (PoC) in that the State, not the facility, develops the PoC. Achieving compliance is the provider's responsibility, whether or not a DPoC was followed. If the facility fails to achieve substantial compliance after complying with the DPoC, the State may impose another alternative sanction (or sanctions) until the facility achieves substantial compliance or it is terminated from the Medicaid program.

B. Basis for Imposition of a DPoC.--Use of a DPoC should be dependent upon causal factors identified by the SA. For example, a DPoC may be an appropriate sanction when a facility has no system in place for detecting abuse and neglect. The DPoC would specify that the facility must develop a system and must have that system in place within a specified time frame.

C. Elements of a DPoC:--The DPoC includes all elements of a traditional plan of correction (see §3006.5C), as well as when the corrective action must be accomplished, and how substantial compliance will be measured.

D. Notice of Imposition of DPoC.--A DPoC may be imposed 15 days after the facility receives notice of this sanction. The date the DPoC is imposed does not mean that all corrections must be completed by that date.

3006.3 Directed In-Service Training.--

A. Purpose.--Directed in-service training is a sanction that may be used when the SA concludes that education is likely to correct the deficiencies. This remedy requires the staff of the ICF-MR to attend in-service training program(s). The purpose of the directed in-service training is to provide knowledge required to achieve compliance and remain in compliance with the Conditions of Participation.

B. Appropriate Resources for Directed In-Service Training Programs.--Facilities should use programs developed by well-established organizations of mental retardation, developmental disabilities, mental health or health services education, such as special education departments in colleges or universities or schools of medicine, State departments/bureaus of mental health/mental retardation or developmental disabilities; Developmental Disabilities Councils; Federally funded State protection and advocacy agencies serving people with developmental disabilities; professional organizations with expertise in developmental disabilities, and a State may provide special consultative services for obtaining this type of training. The SA may also compile a list of resources which can provide directed in-service training and could make this list available to facilities and interested organizations. Facilities may request to use training resources internal to the organization, if the trainer was not directly involved with the area sanctioned. Examples of directed in-service training topics include, but are not limited to, client rights issues, behavior intervention, active treatment, health and safety, and outcome measures.

C. Further Responsibilities.--The facility bears the expense of the directed in-service training. After the training has been completed the SA will assess whether agency staff has demonstrated competency in the area(s) of deficiency and whether compliance has been achieved. If the facility still has not achieved substantial compliance, the State may impose one or more additional sanctions.

D. Notice of Imposition of Directed In-Service Training.--Directed in-service training may be imposed 15 days after the facility receives notice of this sanction. The SA will determine time frames for completion of the directed in-service training.

3006.4 State Monitoring.--

A. Purpose.--A State monitor oversees the correction of cited deficiencies in the facility as a safeguard against further non-compliance when a situation with a potential for jeopardizing health and safety has occurred, but has not risen to the level of immediate jeopardy.

B. Qualifications.--State monitors are identified by the SA as appropriate professionals to monitor cited deficiencies. A State monitor:

- Is an employee or contractor of the SA;
- Is not an employee, designee or contractor of the monitored facility;
- Does not have an immediate family member who is a client of the facility;
- Is not a person who has been terminated for cause by the facility; and
- Is not a former contractor who had a contract cancelled for cause by the facility.

C. When to Impose State Monitoring.--When considering whether or not to impose State monitoring for current noncompliance, the State may want to consider whether:

- The facility has a history of noncompliance which may suggest that it would benefit from external surveillance during corrections;
- The facility has had numerous complaints; or
- The State is concerned that the situation in the facility has the potential to worsen.

States are not limited to considering only these factors and are free to consider any others that would assist them in making remedy determinations.

D. Frequency.--When State monitoring is imposed, the SA appoints a monitor or monitors. Monitoring may occur anytime in a facility; e.g., 24 hours a day, 7 days a week, if necessary or less often such as once a week to monitor specific areas. In all instances, monitors have complete access to all areas of the facility, as necessary, for performance of the monitoring activity. Factors used to decide how often a facility is monitored may include, but are not limited to, the following:

- The nature and seriousness of the deficiency(ies) as specified by the SA; and
- The timing and frequency of when the problems occurred; e.g., mealtimes, evening shifts, daily, etc.

Monitors may be assigned to the facility at these specific times for a specified number of days, as determined by the SA, to ensure corrective action.

E. Duration.--The sanction is discontinued when the facility's provider agreement is terminated or when the facility has demonstrated to the satisfaction of the SA that it is in substantial compliance with the Conditions of Participation.

F. Notice of Imposition of State Monitoring .-- Notice requirements for this sanction state that it may be imposed immediately. No notice is required because the sanction imposes no hardship or expense on the facility.

G. Payment for and Obligation of Funds by a State Monitor.--The facility will not be required to pay the salary of the State monitor; nor will the State monitor have managerial authority to obligate facility funds.

3006.5 Achieving Continuous, Substantial Compliance.--

A. Introduction.--In order to safeguard the health, welfare and safety of individuals served within a facility, it is imperative that a facility not only attain substantial compliance in each area of identified deficiency(ies), but that it maintain/remain in continuous compliance.

B. Duration of a Sanction.--A sanction is discontinued when the facility's provider agreement is terminated or when the facility has demonstrated to the satisfaction of the SA that it is in substantial compliance with the Conditions of Participation.

C. Achieving and Maintaining Substantial Compliance.-- The facilities must establish policies and procedures to remedy deficient practices and to ensure that correction is lasting. Facilities must take the initiative and responsibility for monitoring their own performance continuously to sustain compliance. In order for a PoC to be acceptable, it must include the following elements:

1. Core Elements of PoC:

a. How the corrective action will be accomplished for individuals found to have been affected by the deficient practice;

b. How the facility will identify other individuals who have the potential to be affected by the same deficient practice, and how the facility will act to protect individuals in similar situations;

c. What measures will be put into place or systemic changes made to ensure that the deficient practice will not recur;

d. How the facility will monitor its corrective actions/performance to ensure that the deficient practice is being corrected and will not recur, i.e. what program will be put into place to monitor the continued effectiveness of the systemic change to ensure that solutions are permanent; and

e. When corrective action must be accomplished.

3006.6 Criteria for Review of State Plans for Approval or Disapproval of Alternative Sanctions.--

A. Introduction.--This section implements §1902(i)(1)(B) of the Act and provides guidance to the RO relative to reviewing for approval or disapproval, State plan amendments for alternative enforcement sanctions.

B. Alternative Remedies.--If a State wishes to establish alternative sanctions in addition to the already existing alternative sanction of denial of payment for new admissions, to be used in situations of non-immediate jeopardy, the State plan should describe:

- o Timing and notice requirements;
- o When the remedy will be applied;
- o How the alternative remedy is effective in deterring noncompliance; and
- o Factors considered in selecting the remedy.

## 3007. NONRENEWAL OR AUTOMATIC CANCELLATION OF TIME LIMITED AGREEMENTS (TLAs) FOR ICF/MR FACILITIES

A. General.--Time Limited Agreements (TLAs) of 12 months or less are required by regulations for ICFs/MR (42 CFR 442.15). Like any agreement, a TLA may be terminated. However, unlike other agreements, a TLA may also be nonrenewed or automatically cancelled. The decision to terminate instead of nonrenew or cancel depends on the timing of the onsite survey, i.e., how close in time the survey is to the expiration date or automatic cancellation date, the seriousness of the deficiencies cited, and the possibility of instituting a denial of payments for new admissions which effectively defers the reapproval decision for 11 months.

Nonrenewal and cancellation are preferred alternatives to termination if the termination is effective after the projected renewal or automatic cancellation date. The SA should coordinate title XIX adverse actions with the SMA.

B. Nonrenewal of TLAs.--A nonrenewal is the decision not to renew a TLA following its expiration.

1. Situations Leading To Nonrenewal.--A facility does not qualify for renewal of its agreement if it has been determined, based on resurvey, that it:

- o Has violated the terms of its agreement, the provisions of title XIX, or applicable regulations;
- o Does not substantially meet one or more program requirements (e.g., CoPs for ICFs/MR, or has an unacceptable PoC); or
- o Continues to be substantively out of compliance with the same standard(s) (consistently maintains major deficiency) for ICFs/MR that were found out of compliance during the last survey on which the current certification period was based.

EXCEPTION: A new period of certification may be approved even though the same standard(s) was out of compliance at the time of resurvey if the deficiencies do not substantially limit the facility's ability to furnish adequate care or adversely affect the health and safety of patients and the facility can document that it achieved compliance during the term of the agreement, but for reasons beyond its control was again out of compliance prior to the expiration of the agreement.

2. Timing of Resurvey.--In nonrenewal cases, the SA follows the procedures in the State plan. The SA completes the recertification survey between 60 and 120 days in advance of the expiration of the term of the agreement. The SA and the SMA complete all nonrenewal procedures by the expiration date of the current agreement.

A termination in lieu of nonrenewal is processed if the renewal date is more than:

- o 90 days after finding noncompliance, or

o 23 days after finding noncompliance, if the SA finds there is an immediate and serious threat to patient health and safety.

3. Notice.--In nonrenewal cases, the SMA must give the ICF/MR formal notice of the decision not to enter into a new agreement a full 30 days prior to the date of expiration of its existing agreement.

4. Facility Does Not Want To Renew.--A facility may choose not to renew its agreement. In such cases, the SMA issues any public notice or notice to current residents in accordance with the State plan.

C. Automatic Cancellation Clause for ICFs/MR.--

1. General.--The TLA may contain an automatic cancellation clause. In this case, specify a date that is neither later than the 60th day following the end of the time period specified for such corrections, nor later than the end of the ninth month of the agreement. The cancellation clause provides that if corrections of deficiencies are not made by the date you have specified or substantial progress is not achieved in accordance with an accepted PoC, the agreement automatically terminates on that date. However, if substantial progress is made and an updated PoC accepted, the facility may continue to participate. The SA establishes a control on all cancellation clause agreements to schedule a verification visit as soon as possible after the last date specified in the facility's PoC. Allow processing time in advance of the cancellation date.

The procedures implementing the cancellation clause are similar to those required for an involuntary termination, and, as such, require comparable development, supporting documentation, and internal clearance.

2. Substantial Progress in Correcting Deficiencies Where There Is Cancellation Clause.--"Substantial progress" means that corrections are well underway (i.e., there is tangible and visible progress). For example, if installation of a sprinkler system is required but the system is not yet operating, there should be evidence of progress at the time of the revisit, such as installation of piping. If the only progress by the facility to date has been a loan application which is still pending, this would not constitute substantial progress sufficient to prevent invoking the cancellation clause. However, document extenuating circumstances that are beyond the control of the facility as they can be considered in determining whether to continue the facility in the program.

If the SA verification visit establishes that the facility has made the necessary corrections, or has made significant improvement justifying continuance of the agreement based on an updated PoC, it completes the following forms:

o Form HCFA-2567B for deficiencies which have been corrected. (Complete in accordance with §2732.B.); and

o Form HCFA-2567 for deficiencies not corrected from the previous Form HCFA-2567. (Complete in accordance with §2732.B.)

3. Facility Fails To Make Corrections or Substantial Progress.--Documentation for invoking the cancellation clause need not necessarily be as extensive as that for an involuntary termination. However, while survey efforts may be limited to the confirmation of the continued existence of the deficiencies, the documentation must be clear, convincing, and of the same high quality as that for an involuntary termination action.

However, the basis for invoking this clause is limited to establishing that the facility has not made substantial progress in carrying out its PoC. Whenever a cancellation clause is "invoked" (send notice in accordance with the State plan), implement termination action to remove the facility from participation status. Complete all cancellation procedures by the cancellation date.

When a cancellation clause is invoked, process a Form HCFA-1539 to recommend termination of the agreement with the provider. (See §3005G for termination.)

## 3008 SERVICES AFTER TERMINATION

Payment may be made for a limited time for some patients after the effective dates of termination. (See §§3008.1 and 3008.2.)

### 3008.1 SERVICES AFTER TERMINATION OF A MEDICARE PROVIDER AGREEMENT

Effective the date the provider agreement is terminated, no payment will be made under the agreement. (See 42 CFR 489.55.) However, payment is available for up to 30 days after the effective date of termination for beneficiaries admitted before the effective date of termination for:

- Inpatient hospital services;
- Psychiatric hospital services; and
- SNF services.

Also, payment is available for up to 30 days for care furnished under a plan established before the effective date of termination for:

- Home Health Agency (HHA) services; and
- Hospice care.

### 3008.2 SERVICES FOR WHICH FFP MAY BE CONTINUED AFTER TERMINATION OF A MEDICAID PROVIDER AGREEMENT OR NONRENEWAL OR CANCELLATION OF AN ICF/MR PROVIDER AGREEMENT

FFP may continue for up to 30 days after the effective date of termination (or expiration or cancellation of a provider agreement of an ICF/MR) if the Medicaid beneficiaries were admitted to the entity before the effective date of termination or expiration and the State is making reasonable effort to transfer those beneficiaries to other facilities or to alternate care. (See 42 CFR 441.11.) Services for which FFP may be continues:

- Inpatient hospital services;
- Inpatient hospital services for individuals age 65 or older in institutions for mental disease (IMD);
- NF services;
- NF services for individuals age 65 or older in IMC;
- Inpatient psychiatric services for individuals under age 21; and
- ICF/MR services.

## 3008.3 RELOCATING PATIENTS DISPLACED BY TERMINATION OR CLOSURE

A. General.--There are instances when patients in Medicare and Medicaid long-term care facilities need to be transferred to other facilities. Specific actions, decisions, and events that require the relocation of patients include:

- o Voluntary or involuntary termination of provider agreement;
- o Expiration or renewal of an ICF/MR provider agreement ;
- o The provider's inability to provide care and related services because of fire, natural disaster, loss of staff, or another reason beyond its control;
- o The provider's voluntary termination of participation in Medicaid and/or Medicare; and
- o Closure of a facility.

B. Relocation of Medicaid Patients.--The SMA has the primary responsibility for relocating Medicaid patients and for ensuring their safe and orderly transfer from a facility that no longer participates in Medicaid to a participating facility. This is because the State remains responsible for the care and services provided to Medicaid patients. The State's transfer policies must:

- o Consider the nature and severity of the facility's failure to meet standards;
- o Consider the availability of alternative facilities;
- o Ensure that the situation is explained to the recipient and the recipient is permitted to exercise an informed choice as to whether he or she wishes to move and, if so, to which available facility.
- o Provide that qualified personnel will assess patients' medical and psychological condition and needs, including the necessity to prepare the patient for transfer;
- o Provide for adequate and appropriate transportation on the day the patient is moved; and
- o Apprise the receiving facility of the patient's condition and needs.

C. Relocation Activities.--The State should develop a long term care patient relocation plan for the orderly transfer of patients. The plan should provide for:

- o Decisions to be made on relocation of patients on a case-by-case basis;
- o Independent current assessment of the patient's need for institutional care and the level and type of care needed;
- o Procedures they will employ to ensure that the transferring facility maintains acceptable health care standards and takes necessary precautions to minimize fire hazards;
- o Description of the organization and staffing necessary to implement the plan; and
- o Necessary agreements and approvals for the transfer of the patient.

The State plan should have a degree of flexibility that will enable it to be used for the relocation of any number of patients. The frequency with which States will implement their patient relocation plans will vary considerably from State to State. However, it should be developed as an ongoing, standard operating procedure which can be implemented quickly and efficiently. The plan should be developed by the State Medicaid agency in conjunction with the SA.

## 3010. TERMINATION PROCEDURES - IMMEDIATE AND SERIOUS THREAT TO PATIENT HEALTH AND SAFETY (MEDICARE) (See §§7307 - 7309 for SNFs/NFs.)

A. Substantial Noncompliance With Program Requirements Which Poses Immediate and Serious Threat To Patient Health or Safety.--"Immediate and serious threat" is interpreted as a crisis situation in which the health and safety of patients is at risk. Generally, it is a deficient practice which indicates the operator's inability to furnish safe care and services, although it may not have resulted in actual harm. The threat of probable harm is real and important and could be perceived as something which will result in potentially severe temporary or permanent injury, disability, or death. Therefore, it must be perceived as something which is likely to occur in the very near future. If the patients are not protected effectively from the threat, or if the threat is not removed, there is a high probability that serious harm or injury could occur at any time or already has occurred and may occur again.

A list of operational definitions of what can constitute an immediate and serious threat to patient health and safety is presented as a guide to be used by all surveyors. (See Appendix Q.) Generally, the criteria applies to most providers and suppliers, although some criteria may apply to only certain types of providers or suppliers. The operational definitions are not intended to be all-inclusive, nor are they intended to inhibit the professional judgment of the surveyors. Surveyors may find that an immediate and serious threat does not exist when the definitions seem to apply or that such a threat does exist even though the definitions do not address the situation or condition observed by the surveyors.

The key factor in the use of the immediate and serious threat termination authority is, as the name implies, limited to immediate and serious. The threat must be present when you are onsite and must be of such magnitude as to seriously jeopardize a patient's health and safety. There should be no other application of immediate and serious threat terminations. Do not use these procedures to enforce compliance quickly on more routine deficiencies.

B. Processing of Immediate and Serious Threat Terminations.--When an immediate and serious threat to patient health or safety is documented, the SA and RO complete termination procedures within 23 calendar days. Processing times given here are the maximum allowed. Do not postpone or stop the procedure unless compliance is achieved and documented through on-site verification. If there is a credible allegation that the threat or deficiency has been corrected, the SA conducts a revisit prior to termination if possible. Do not use this procedure if there is an ICF/MR time-limited provider agreement that is subject to cancellation or nonrenewal within 23 days after the survey. In such a case, process the cancellation or nonrenewal. (See §3007.)

When HCFA surveys psychiatric hospitals and determines that an immediate and serious threat to patient health or safety exists, the RO completes termination procedures within 23 calendar days. On the last day of the survey, HCFA surveyors telephone Central Office (CO) to certify noncompliance and that an immediate and serious threat exists. CO immediately notifies the RO of the HCFA surveyors' findings. HCFA surveyors discuss their findings with the provider and tell the providers that they are mailing the RO by overnight express mail completed Forms HCFA-1537A and HCFA-2567. A copy is also mailed to CO for review. The RO reviews the survey package (Forms HCFA-1537A and HCFA-2567), and if it determines nomcompliance, it mails Form HCFA-2567 to the provider. After doing so, the RO follows the 23-day termination procedure as outlined below beginning with the fifth working day.

1. Date of Survey.--The date of the survey is the date on which the entire survey is completed, regardless of when the exit conference is held.

2. Second Working Day.--No later than 2 working days following the survey date. The SA:

- Telephones the RO that it is certifying noncompliance and that an immediate and serious threat exists; and

- Notifies the provider/supplier (by telegram or overnight express mail) of its deficiencies and inform the provider/supplier that it is recommending termination to the RO, which will issue a formal notice. The notice advises the provider/supplier of its right to due process, the expected schedule for termination action, and that the deficiency must be corrected and verified by the SA to halt the termination. If the provider also participates in Medicaid, the SA notifies the SMA of its certification of noncompliance.

3. Third Working Day.--The SA forwards all supporting documentation to the RO (e.g., statement of deficiencies, correspondence, contact reports, Form HCFA-1539). The SA forwards the information by overnight mail to assure that the RO receives it in time to meet the 5-day deadline. Upon receipt of the SA information, the RO reviews the documents and makes its determination of noncompliance.

4. Fifth Working Day.--The provider/supplier and the public are then notified by the RO of the proposed termination action by the most expeditious means available. A press release to the radio and television stations serving the area in which the facility or instituiton is locted is acceptable if a newspaper notice cannot be arranged in the time allotted. Notice must be made at least 2 days prior to the effective date of termination. (See 42 CFR 489.54(c).)

5. Tenth Working Day.--If official notification of all deficiencies, i.e., Form HCFA-2567, was not given on the second working day, the SA forwards copies of Form HCFA-2567 to the provider/supplier, the RO, and SMA, if the provider participates in Medicaid. The SA retains a copy for its records.

6. Twenty-Third Calendar Day.--The termination takes effect unless compliance is achieved or threat is removed. If the threat has been removed, but deficiencies still exist at the Condition level, the SA gives the provider/supplier up to 67 more days, or 90 days total (23 plus 67). These dates are maximum times, and participation may be terminated earlier if processing allows. However, the RO must adhere to both the provider/supplier and public notice timeframes.

Where a certification survey, complaint survey, or revisit has been conducted, the SA may certify that the immediate and serious threat has been removed and recommend that the immediate and serious threat action be rescinded. If the RO disagrees based upon its review of the documentation, the RO informs the provider via telephone or letter of the need for further development and that a revisit will be conducted by a RO and SA surveyor to ascertain whether or not the threat has been removed. If possible, the RO should utilize the SA surveyor who conducted the prior revisit. Under no circumstances should the RO reverse a SA recommendation that an immediate and serious threat has been removed or not removed unless the determination is made on the basis of an onsite determination by Federal surveyors.

Medicaid agreements with facilities that concurrently participate in Medicare should be terminated on the same date the Medicare agreement is terminated. Where State law permits, Medicaid-only facilities should be terminated by the State within the above time limits. For NFs that also participate as SNFs, the State's timing of termination shall control. (See 42 CFR 488.452.)

3012. TERMINATION PROCEDURES - NONCOMPLIANCE WITH ONE OR MORE CoPs OR CONDITIONS FOR COVERAGE AND CITED DEFICIENCIES LIMIT CAPACITY OF PROVIDER/SUPPLIER TO FURNISH ADEQUATE LEVEL OR QUALITY OF CARE (MEDICARE)--SEE §7310 - 7313 for SNFs/NFs

Failure to substantially meet one or more Conditions is a cause for termination of participation. "Substantially," for purposes of this section, is defined as meeting the applicable CoPs or Conditions for Coverage. Any provider/supplier that does not substantially meet the Conditions is considered to be limited in its capacity to furnish services at an adequate level or quality. Compliance with Conditions; i.e., condition level deficiencies, can never be certified based upon a PoC or acceptable progress since the law specifically requires that all CoPs or Conditions for Coverage must be met. If there is not an immediate and serious threat to patient health or safety, the RO and the SA use the following schedule:

1. Date of Survey.--The date of the survey is the date on which the entire survey is completed regardless of when the exit conference is held.

2. Fifteenth Day.--The SA notifies the provider/supplier and RO of cited deficiencies. The SA informs it in writing that there is a determination of noncompliance and that it is recommending termination to be effective within 90 days from the date of the survey. (Include the recommended termination date in the letter.) The SA informs it that the termination process provides an opportunity to make corrections and that if compliance is achieved, it is to notify the SA immediately. The SA should state that it will make a revisit within 45 days of the survey if a credible allegation of compliance is received. Termination takes effect as planned if compliance is not achieved. This notice serves as a warning letter to the provider or supplier.

3. Forty-Fifth Day.--If the facility has made a credible allegation of compliance (see §3016.A.), the SA conducts a revisit to determine whether compliance or acceptable progress has been achieved. Only 2 revisits are permitted; one within 45 days and one between the 46th and 90th days. If a second credible allegation of compliance is made prior to the effective date of termination, the SA telephones the RO and submits documentation to support the second revisit (only the second revisit is subject to RO approval). If the facility fails to make a credible allegation, no revisit is necessary.

4. Fifty-Fifth Day.--If compliance has not been achieved, the SA certifies noncompliance. The SA forwards the certification and supporting documentation to the RO. The SA notifies the provider/supplier that termination is recommended and alerts the SMA if the provider/supplier is also participating in Medicaid.

5. Sixty-Fifth Day.--Within 65 calendar days following the date of survey, the RO determines whether survey findings continue to support a determination of noncompliance.

6. Seventieth Day.--The RO sends an official termination notice to the provider/supplier, the public, and the SMA if the provider/supplier also participates in Medicaid. Notices must be made at least 15 days before the effective date of termination.

7. Ninetieth Day.--Termination takes effect if compliance is not achieved. It can take effect in fewer than 90 calendar days if required procedures are completed.

NOTE: All timeframes are maximum. The RO may terminate more quickly as long as the regulatory requirements for notification of the public and provider are satisfied.

## 3012.1 TERMINATION OF PSYCHIATRIC HOSPITALS BASED ON HCFA MENTAL HEALTH SURVEYORS' SURVEY

The termination process for psychiatric hospitals utilizing HCFA mental health surveyors is consistent with the 90 day timeframe for other providers. However, due to the additional administrative process of sending the survey findings to the CO, day 1 of the 90 day termination timeframe begins on the date the RO receives the psychiatric survey report form findings from CO. The HCFA mental health surveyors send the survey findings within 10 working days from the last day of survey to the CO, not to SAs and ROs. The CO reviews the survey findings for appropriateness and completeness of documentation and forwards them to the RO for final review and determination of compliance or noncompliance. If either of the two special psychiatric conditions are not in compliance (42 CFR 482.61 and Part 482.62), the 90-day termination procedures begin the day the RO receives the survey report.

Follow the termination procedures and timeframes below:

- First Day.--Date of RO receipt of the survey findings from CO.

- First - Fifteenth Day.--The RO reviews the survey report for adequacy of documentation to determine whether the documentation supports a finding of noncompliance with either psychiatric hospital requirement. (See 42 CFR Part 482.61 and 482.62.)

The RO notifies the CO via telephone if it does not concur with the HCFA mental health surveyors' findings regarding noncompliance with the psychiatric hospital requirements. Note that day 1 of the termination procedures begins the day the RO receives the completed psychiatric hospital survey report, not the day the RO reviewed the report for concurrence or nonconcurrence with the findings.

- Fifteenth Day.--The RO notifies the provider of the cited deficiencies. The RO informs the provider in writing that a determination of noncompliance has been made and that termination will be effective 90 days from the RO's receipt of the survey report form (see Exhibit 180). Also the RO informs the provider that the termination process provides the opportunity to make corrections, and that if it reasonably believes that compliance has been achieved, it should notify the RO immediately. Explain that a revisit will be made within 45 days from the RO's receipt of the survey report form if a credible allegation of compliance is received. However, termination takes effect as planned if compliance is not achieved. This notice serves as a warning notice to the hospital, and it contains the proposed termination date.

- Forty-Fifth Day.--If the provider makes a credible allegation of compliance, the RO notifies CO and request a revisit utilizing the HCFA mental health surveyors. The revisit to determine whether compliance has been achieved is to be conducted by the 45th day. If a provider has not alleged compliance by the 45th day, it is not precluded from making an initial credible allegation between the 46th and 90th day.

- Fifty-Fifth Day.--If a revisit has been made and compliance has not been achieved, the RO notifies the provider of the deficiencies that are not corrected and of any new deficiencies noted on the revisit.

- Forty-Sixth - Ninetieth Day.--If the provider makes a credible allegation of compliance, the RO notifies the CO to schedule a second revisit to be conducted before the ninetieth day to determine whether compliance has been achieved.

- Seventieth Day.--The RO sends an official termination notice to the hospital and a copy to the SMA if the provider also participates in the Medicaid program.

- Seventy-Fifth Day.--The RO publishes the public notice.

o Ninetieth Day.--Termination takes effect if compliance has not been achieved. It can take effect in less than 90 calendar days if all required procedures have been completed.

## 3012.2 TERMINATION OF ORGAN PROCUREMENT ORGANIZATIONS (OPO)

If an OPO voluntarily terminates its agreement, it must send a written notice with the proposed effective date. The RO approves the proposed termination date or set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed date. When an OPO ceases to furnish organ procurement services to its service area, this constitutes a voluntary termination by the OPO. The RO determines the effective date and notifies the OPO.

OPOs are involuntarily terminated when they fail to meet one or more conditions for coverage or are not in substantial compliance with any other applicable Federal regulations or provisions of titles XI, XVII, or XIX of the Act. The RO terminates an OPO immediately when there is an urgent need, such as the discovery of unsound medical practices. The RO follows the termination procedures detailed below. The effective date of the termination can be anytime during the 2-year designation period, depending on when it is determined that the OPO is out of compliance with the conditions for coverage. The RO notifies CO, the fiscal intermediary and the Organ Procurement Transplantation Network (OPTN) that the OPO has been terminated and the date of the termination.

A. Termination Procedures -- The RO:

1. Informs the OPO of the timeframes for submitting additional data to support compliance and sends Model Letter: Organ Procurement Organization Corrective Action Notice. (See Exhibit 176.)

2. Determines compliance if a credible allegation of compliance is received. Failure to achieve compliance will result in termination.

3. Notifies the OPO whether or not they have achieved compliance with the Conditions for Coverage. If the OPO achieves compliance send Model Letter: Organ Procurement Organization Approval. (See Exhibit 172.) If the OPO fails to achieve compliance initiate termination proceduresand send Model Letter: Organ Procurement Organization Notice of Termination. (See Exhibit 175.) The letter informs the OPO of:

    a. The legal basis for termination;
    b. The effective date of the termination;
    c. The deficiencies cited and the requirements not met; and
    d. Appeal rights.

4. Opens the service area for competition. (See §2817 and Exhibit 173.)

5. Publishes a public notice in the newspapers (see Exhibit 174). Sends copies of the official termination notice with a cover letter to:

    a. Association of Organ Procurement Organizations
    8110 Gatehouse Road, Suite 101 West
    Falls Church, VA 22042;

b. Current Organ Procurement and Transplantation Network
The current OPTN is:
UNOS
1100 Boulders Parkway, Suite 500
Post Office Box 13770
Richmond, VA 23225);

c. CO;

d. Hospitals that have a working relationship with the OPO;

e. Bordering OPOs;

f. Medicaid/Medicare State Agencies; and

g. Fiscal intermediary of the terminated OPO.

B. Reinstatement Procedures

The OPO may appeal the termination decision under HCFA regulations at 42 CFR 498. The OPO must submit its request in writing to the appropriate RO within 60 days of receipt of the termination notice. The request must include the issue(s) or finding(s) of fact, which are in disagreement and the reasons for the disagreement. The OPO may also submit written evidence and statements that are relevant and material within a reasonable time after the request for reconsideration. Once the service area is open to new applicants, the terminated OPO may apply for approval. If the terminated OPO applies, it is essential for the OPO to demonstrate how it achieved and how it will maintain compliance with the requirements.

## 3014. RO TERMINATION ACTION BASED ON ONSITE FEDERAL SURVEY OF MEDICARE PROVIDER OR SUPPLIER (EXCLUDING SNFs)

When an immediate and serious threat to patient health and safety or noncompliance with one or more Conditions is determined by a RO survey team, whether in the course of a regular scheduled Federal monitoring survey (full or partial), in response to a complaint, or as part of the validation effort of an accredited facility, the RO initiates termination procedures provided in §§3010 or 3012. The RO notifies the SA and the SMA of the action being taken. The RO completes the Certification and Transmittal, Form HCFA-1539, to assure the data in Online Survey, Certification and Reporting System (OSCAR) is updated to include the termination action. (See Chapter 7 for SNFs and NFs.)

## 3016. INTERVENING ACTIONS THAT DO NOT POSTPONE OR DELAY TERMINATION TIMETABLE-- (INCLUDES CREDIBLE ALLEGATIONS)

A. Credible Allegation of Compliance.--A credible allegation is a statement or documentation:

- That is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation; and

- That indicates resolution of the problems.

If the provider/supplier makes an additional credible allegation that the deficiency(ies) is corrected following an earlier revisit or between the 46th and 90th day prior to the effective date of termination, notify the RO by telephone. The SA submits all evidence or documentation regarding the facility's allegation and its recommendation regarding the facility's alleged compliance. The RO makes a determination whether a second revisit is appropriate.

The SA conducts a second revisit if one is approved by the RO. The SA forwards all supporting documentation, along with Form HCFA-1539, certifying compliance/noncompliance to the RO immediately following the revisit.

Only compliance can rescind a termination action.

B. Informal Hearings Do Not Interrupt Timetable.--The process may not be postponed to accommodate informal hearings or meetings or to give the provider additional time to achieve compliance. Such discussion may, however, be conducted within the procedural time limits in §3012, as deemed appropriate by the RO. This 90-day procedure provides adequate time for the provider to achieve compliance if the decision by the RO is to wait the full time allowed and if the well-being of patients is not jeopardized in the interim.

C. Acceleration of Timetable.--The SA switches from the 90-day procedures in §3012 to the accelerated procedures in §3010 at any point when there is an immediate threat to patient health and safety.

D. Termination Development Coinciding With Change of Ownership (CHOW) Development.--A CHOW does not affect completion of a termination action. The SA does not postpone any required termination, nor does it solicit a PoC from the new owner. Court appointed receivership is not a basis for cessation of the termination process. Following termination, the new owner may, however, request approval for participation as a new provider, subject to reasonable assurance provisions (reasonable assurance only for Medicare). (See §2016.)

E. Disagreement Over Deficiencies.--A provider that disagrees with any SA finding regarding a cited deficiency or an acceptable PoC should be advised to annotate its position on the PoC, and should specify why the SA's citation is not correct. This information does not interrupt the termination process, but is publicly disclosable and is included in the documentation considered during subsequent reconsideration and hearings.

## 3016.1. PROVIDER UNDERGOES CHOW DURING TERMINATION PROCEEDINGS

If the SA learns that the provider is initiating a CHOW, it does not interrupt completion of its documentation of the certification of noncompliance. The SA continues to document noncompliance of the previous owner. The SA does not send a Form HCFA-1539 to report the change.

## 3018. TERMINATION - SA DOCUMENTATION REQUIREMENTS

A. Documentation To Support Proposed Termination.--All documents to support a proposed termination must be complete, accurate, and logical in sequence. Each document must be dated and signed by the preparer or indicate the date of receipt in the SA. The documentation must be supported by a complete current survey report or, in the case of an HHA, required HCFA forms.

1. Current Survey Report.--The SA reviews the current survey report or required forms to ensure that all items are properly completed. If there are any changes or erasures, the SA initials the item and explain the basis for the modification in the explanatory remarks column.

The SA includes the following information in the explanatory remarks column for each item checked "not met:"

- A description of the deficiency;

- Whether the deficiency existed during the previous survey and whether compliance was achieved; and

o Current PoCs, if any.

In addition, the SA includes with the package an estimate of whether there is a prospect of compliance with all eligibility requirements within the time limits and the basis for this opinion.

2. Previous Survey Reports.--The SA reviews previous survey reports for consistency. If a deficiency is reported on the current survey report that has obviously existed for some time, explain why it was not reported previously; e.g., serious structural defects, inadequate fire escapes.

The SA explains any conclusions that might be questioned, especially if certain requirements are being weighed heavily. For example:

o The majority of standards are checked "not met," yet the Condition is found in compliance; or

o A Condition is found not in compliance based upon the relationship of standards or other deficiencies not being met.

B. Record of Contacts With Providers/Suppliers.--The SA includes in documentation copies of communications and written reports of oral communications with providers/suppliers including the date of contact, the person involved, the purpose, and the content of the communication. Also, the SA includes reports of investigations of complaints.

C. Notification To Provider/Supplier of Deficiencies and Recommendation of Termination.--The SA includes in the file a copy of the letter notifying the provider/supplier of the deficiencies found on the survey and advising that failure to correct will result in a recommendation for termination and includes copies of any other SA notices to the provider/supplier.

## 3020. ADDITIONAL SA COMMUNICATIONS WITH PROVIDERS/SUPPLIERS

After the SA forwards the certification of noncompliance, it clears any further communications to the provider/supplier with the RO. Unrecorded visits, surveys, or correctional allegations that were not reported before final termination action could cause embarrassment or even result in failure to sustain the termination action. Even after final termination action, any additional contacts may be pertinent to proper handling of the case. The SA notifies the RO of any such contacts.

## 3022. NOTICE OF TERMINATION (MEDICARE)

The RO notifies the provider/supplier of its termination by letter at least 15 days before the effective date of the termination. (In the case of a provider or supplier with deficiencies that pose an immediate and serious threat to residents' health and safety, HCFA gives notice of the termination at least 2 days before the effective date of the termination.) (See 42 CFR 489.53.) The RO mails a copy of the letter to the SA, the SMA (if appropriate), and the intermediary or carrier servicing the facility. The notification contains information regarding the provider's/supplier's right to appeal the termination. In the case of a provider termination, the RO concurrently notifies the public giving the reason for and the effective date of the termination. The only suppliers requiring public termination notices are RHCs (42 CFR 405.2404), ASCs (42 CFR 416.35), and FQHCs (42 CFR 405.2442). Public notices for other suppliers are optional at the discretion of the RO.

## 3024. RO TERMINATION PROCESSING SEQUENCE - NONCOMPLIANCE WITH CoPs OR CONDITIONS FOR COVERAGE (EXCLUDING SNFs)

Upon receipt of the SA's unfavorable certification, the RO:

A. Establishes controls for processing the termination;

B. Performs an initial documentary review to make certain that copies of all pertinent surveys, statements of deficiencies, plans of correction (if submitted by the provider), and other necessary documents are included and that all relevant issues are resolved. When unable to determine the relationship of cited deficiencies to the quality of services or the health and safety of patients, the RO requests further SA development. If necessary, the RO retains the file and phones the SA for the additional documentation needed;

C. Does a substantive review, resolves all substantive discrepancies and disputes, assesses the severity of the provider's/supplier's noncompliance, and makes its determination. The RO consults with LSC specialists in the RO, if necessary. See discussion in §3026 concerning how to treat key documents in making your determination;

D. The RO prepares the Termination Notice (Exhibits 181 and 182) and Newspaper Notice (Exhibit 183) and any supplemental press releases, if planned. The RO forwards a copy of its notice to the SMA, if appropriate; and

E. Inserts the effective date of termination in the notice and make the necessary arrangements for public notice. To give both the provider and the public sufficient advance notice of termination of a provider's agreement (at least 2 days if there is immediate jeopardy or at least 15 days if there is no immediate jeopardy), determines the effective date of termination as follows:

o Allows sufficient time for delivery of the notice to the provider, depending on the provider's location and the method of notification, i.e., letter, overnite mail, or electronic means.

o Determines the time needed for actual public notice by contacting the local newspaper or radio and television stations to determine their deadlines. (See §3034);

o Allows for receipt of the notice by the provider prior to publication of the public notice and assure that the public receives at least 2 days if immediate jeopardy exists, otherwise 15 days notice prior to the date of termination;

o Mails the termination notice to the provider (return receipt requested); and

o Notifies the SMA of action taken against Medicaid ICFs/MR and the effective dates if termination action is taken pursuant to §3000.C.3. When the termination action is taken, the RO mails the informational copies to the following offices:

- Division of Medicare;
- Division of Medicaid;
- CO;
- Intermediary;
- SA;
- SMA;
- Regional Director, Department of Health and Human Services (DHHS); and
- State Ombudsman.

## 3026. SIGNIFICANCE OF DOCUMENTARY EVIDENCE IN DETERMINING NONCOMPLIANCE

The RO uses the following documentation in determining compliance with the Medicare Federal CoPs or Conditions for Coverage or Requirements of Participation.

A. Statement of Deficiencies.--This statement constitutes evidence that the provider/supplier was notified of the specific deficiencies. These deficiencies are to be written as required by the Principles of Documentation. This assures that the statement provides accurate descriptions of the deficiencies and interpretations of Federal Medicare requirements that are not met. Otherwise, it might be alleged at a hearing that the termination action was based on error.

B. Plan of Correction (PoC).--The PoC presents evidence that the provider is unable or unwilling to achieve compliance in a reasonable amount of time. When a provider disagrees with a SA or RO finding of a cited deficiency or that a PoC is unacceptable, it is to state the basis for disagreement on Form HCFA-2567. Whenever possible, the provider is to reference the specific regulatory provision involved in the disputed issue and why they believe the provision is met. The RO reviews all of the documentation including the survey findings and the documentation presented by the facility before making a determination. (If the RO determines that a deficiency did not exist, it is removed from Form HCFA-2567.)

C. Revisit Reports and Subsequent Statements of Deficiencies.--This is the SA's report of any revisit which was made to the provider/supplier following the survey which found the provider/supplier out of compliance.

D. SA Certification (Completed Certification and Transmittal (Form HCFA-1539)).--This is the SA's certification as to whether the Medicare health and safety requirements were met at the time of survey. It also indicates that the SA completed the required actions and decisions.

E. Survey Reports.--Survey reports are the surveyor's written records of findings during surveys that are primary evidence for the RO’s determination.

F. Documents of Collateral Evidence.--When obtainable, the RO adds such items as copies of pertinent provider records, correspondence, and State licensure information to the termination file to resolve or forestall conflicts of factual information elsewhere in the file and to support the adverse findings in the determination. Documentation can include verified complaint information.

G. Notice of Termination.--An adjudicative determination is consummated in an official notice of determination given to the parties whose rights are at issue. The determination becomes official when the notice (the formal termination letter) is mailed. It is essential that the notice be correct, not only in its procedural rendition, but also in the substance of the decision reported, since the receiving entity, as well as appellate authorities and courts, will treat it as the official "determination."

## 3028. DOCUMENTATION GUIDE LIST - TERMINATION FOR NONCOMPLIANCE WITH §§1866(b)(2)(A) AND (C)

A. Documentation Appropriate To All Cases.--The RO uses the following to document recommendations for termination of a provider agreement pursuant to §§1866(b)(2)(A) and (C) of the Act:

- Copy of the letter to the provider advising it of the recommendation for termination (include the certified mail return receipt);

o Copy of Health Insurance Benefits Agreement, Form HCFA-1561, filed by the provider and accepted for filing in the RO;

o Copy of the Letter of Acceptance of Agreement forwarded to the provider;

o All pertinent beneficiary complaints received;

o All pertinent violation reports made by the intermediary, Social Security office, etc;

o Detailed reports of all pertinent intermediary efforts (i.e., dates, topic, reactions, results) and copies of related correspondence from the intermediary to the provider, including copies of any pertinent "provider letters" that may have been issued by the intermediary to the provider;

o Intermediary report on the current payment status of the provider, e.g., suspended, reduced, in current payment status. If the recommendation is based on failure to file annual cost reports, this item may be included as part of §3028.C;

o Detailed reports of all pertinent RO efforts (i.e., dates, topics, results, etc.) and copies of related correspondence from the RO to the provider; and

o All pertinent letters (or detailed records of visits or phone calls) received by the intermediary or by the RO from the provider.

B. Additional Documentation - Charging For Covered Services and/or Refusing To Refund Incorrect Collections.--Additional documentation for the RO to use in making a determination of noncompliance includes:

o Name, address, claim number, and dates of stay of any involved Medicare beneficiary known to have been furnished covered services by the provider;

o Where the services in question were furnished in a SNF, information relating to the beneficiary's prior qualifying hospital stay, including if appropriate, copies of the Medicare billing submitted for the period of hospitalization;

o Copies of any bills, receipts, letters, that were received by the beneficiary from the provider requesting payment, including, if available, a description of the services furnished to assure that payment was requested for "covered services";

o Copies of any checks, money orders, receipts, etc., which show payment to the provider by the beneficiary;

o Copies of any materials available which would show the payment conditions under which the beneficiary was furnished services, e.g., a contract of admittance;

o Copies of all pertinent "request for payment" forms that may have been filed by the provider for services furnished to the beneficiary during the period in question. If requests for payment were filed and program payment was received by the provider, the RO secures a written statement from the intermediary which shows that program payment (and the amount) was made to the provider on behalf of the beneficiary. For those cases where program payment has not been made (including cases where the provider has not filed a request for payment), secure a written opinion from the intermediary (based on available medical records and/or billings) as to the probability for making program payment;

o Copies of any requests by the beneficiary for the return of amounts paid to the provider for covered services, including any reply by the provider; and

o Authorization for the United States to act on behalf of the beneficiary. If the beneficiary has instituted any legal action to recover amounts paid to the provider, the RO does not secure the authorization. Use the following format:

Authorization

I hereby request that the United States act on my behalf to recover from (name of provider) amounts which I paid to said (hospital, nursing home, etc.) for services covered under title XVIII of the Social Security Act, popularly known as Medicare.

I hereby affirm that I am an eligible Medicare beneficiary and that as such I was a patient at said (hospital, etc.) from _____ to ____(insert dates) and that I paid said (hospital, etc.) $ ____(insert amount paid) for services rendered during this period.

Signed

Medicare No.

All of the information listed above should be obtained by the Division of Medicare as part of its responsibility in monitoring Medicare fiscal intermediaries.

C. Additional Documentation - Failure To File Cost Reports.--The RO provides a listing of all pertinent health insurance checks, including check number, date, amount, disposition, drawn payable to the provider by the intermediary. (This information is to be shown under an intermediary letterhead and signed by a responsible person.) The RO includes a breakdown to show separately the period ("from ____ to ____") that related to these payments, including any offset against payments which may be due the provider, the total payment for the period involved, and the method of payment, e.g., periodic interim payments.

The RO reviews the data and material received from the intermediary and the additional documentation listed here and in subsection A, above, to avoid a duplication of development and documentation. If the case file shows that the provider has also failed to make satisfactory refund of overpayments, see subsection D.

D. Additional Documentation - Failure To Make Satisfactory Overpayment Arrangements.--The RO reviews the data and material received from the intermediary and the documentation listed in subsection A to avoid a duplication of development and documentation. If the case file shows that the provider has also failed to file a cost report, see subsection C.

Section 1866(b)(2)(A) of the Act provides the authority to terminate the agreement of a provider which has failed to refund a substantial overpayment. For this purpose, when a provider has failed to make satisfactory arrangements for repayment, the sum of $1,000 or more may be viewed as a substantial overpayment. However, when considering termination of an agreement, the RO takes into consideration the full circumstances of the particular case.

E. Additional Documentation - Admission Policies and Practices.--As provided in 42 CFR 489.53(a)(2), participation of a provider which voluntarily files an agreement to participate in the Medicare program contemplates that the provider accepts beneficiaries for care and treatment. If a participating provider has any restrictions on the types of services it makes available and/or the type of health conditions that it accepts, or has any other criteria relating to the acceptance of persons for care and treatment, it is expected that such restrictions or criteria, if made applicable to Medicare beneficiaries, are applied in the same manner to all other persons seeking care and treatment. A provider's admission policies and practices that are inconsistent with the provider agreement objectives set forth in this paragraph may be the basis for termination of participation by the Secretary pursuant to §1866(b)(2)(A) of the Act and 42 CFR Part 489.53(a)(2).

The amount of documentation for a provider's failure to meet the above requirements is dictated by the circumstances of the particular case. Thus, the RO attempts to secure from all available sources (e.g., beneficiaries, providers, intermediaries) any information which would be useful in making the determination.

## 3030. PROVIDER AGREEMENT TERMINATIONS - NONCOMPLIANCE WITH §§1866(b)(2)(A) AND (C)

A. Cause For Termination.--Under the provisions of §§1866(b)(2)(A) and (C) of the Act (also 42 CFR 489.53), the Secretary may terminate an agreement with a provider of services if it is determined that the provider:

- o Is not complying substantially with the terms of the agreement, the provisions of title XVIII, or regulations promulgated thereunder;
- o Has failed to supply information necessary to determine whether payments are or were due and the amounts of such payments;
- o Refuses to permit examination of fiscal and other records (including medical records) necessary for the verification of information furnished as a basis for claiming payment under the Medicare program; or
- o Refuses to permit photocopying of any records or other information necessary to determine or verify compliance with participation requirements.

B. Preparing Termination Cases.--the RO apprises the provider of its obligations and the consequences of continued violation before considering the need for terminating the agreement. Contacts with the provider may be made through the intermediary or by the RO staff, at the ROs discretion. In corresponding with the provider, the RO uses certified mail with a return receipt requested.

The RO bases termination on documentation that supports a finding that the provider is not complying with the terms of the agreement or the provisions of title XVIII and implementing regulations.

C. Preliminary Notice To Provider.--The RO notifies the provider by letter that the findings and recommendations are being considered and that, if the findings are affirmed, the provider will receive official notice of termination of participation and the effective date on which the agreement is to be terminated. The RO advises the provider that when the official notice is released, it may be changed only if the determination is reversed upon appeal. Also the RO advises the provider to contact your office if it has taken steps to correct the violation or has definite plans for doing so.

D. Violation of §§1866(b)(2)(A) and (C).--The RO notifies the provider that notice will be placed in the local newspaper(s) advising the public in accordance with the provisions of title XVIII. The RO explains the effect of the termination with respect to services furnished on or after the termination date, and advise the provider of the right to a hearing and the manner of filing for it. After the official notice of termination of participation is released to the provider, the RO proceeds with publication of the public notice. (See §§3034 and 3036.)

On the day before the public notice is published, the RO calls the intermediary and advises them of the termination. The RO cautions the intermediary not to divulge this information before the notice is published. Following publication, the RO formally notifies the SA.

## 3032. TERMINATION FOR VIOLATIONS OF §§1866(a)(1)(E), (F), (G), AND (H)

Under the provisions of §§1866(a)(1)(E), (F), (G), and (H) of the Act, the Secretary may terminate an agreement with a provider of services if it is determined that the provider:

- Fails to release data upon request to an organization having a PRO contract with the Secretary under Part B of title XI;
- Fails to maintain an agreement with the organization having a PRO contract with the Secretary under Part B of title XI;
- Has charged an individual for inpatient hospital services for which the individual was entitled to have payment made under Part A, pursuant to §§1886(b) and (d); or
- Fails to furnish all services (except for physician services as defined in §§1862(a)(14) and 1861(w)(1) of the Act) and items for which payment is made under §1866(a)(1)(G) of the Act.

## 3034. PUBLIC NOTICE - INVOLUNTARY TERMINATION

The RO arranges to publish a notice in the local newspaper(s) announcing the termination and the reasons for termination of providers. Public notices are not required for suppliers, except in the case of RHCs (42 CFR 405.2404(d)), Ambulatory Surgical Centers (ASCs) (42 CFR 416.35(d)), and Federally Qualified Health Centers (FQHCs) (42 CFR 405.2442). The RO may place public notices for the termination of other suppliers at its discretion.

A. For Providers.--

MEDICARE NOTICE TO THE PUBLIC:

Notice is hereby given that the agreement between the (facility/address), and the Secretary of Health and Human Services, as a provider of services in the Health Insurance for the Aged and Disabled Program (Medicare) is to be terminated at the close of (date of termination).

B. For Suppliers.--

MEDICARE NOTICE TO THE PUBLIC:

Notice is hereby given that effective at the close of (date of termination) the (name and address of facility) is no longer approved for participation in the Medicare program as a supplier of (type of services).

The RO inserts the reasons for termination in the format of the following example:

The (name of provider) does not comply with the Medicare (Condition of Participation/Requirements of Participation/Condition for Coverage) pertaining to (Condition(s) or Requirement(s) (for SNFs) out of compliance).

Add one of the paragraphs below, depending on the type of provider being terminated:

C. For Hospitals and SNFs.--"The Medicare program will not make payment for inpatient hospital services (or skilled nursing facility services) furnished to patients who are admitted after the close of (date of termination). For patients admitted on (date of termination), or earlier, payment may continue for up to 30 days of inpatient hospital services (or skilled nursing facility services) furnished after (date of termination)."

D. For HHAs and Hospices.--"The Medicare program will not make payment for [home health] [hospice] services furnished to patients whose plan of treatment was established after the close of (date of termination). For patients whose plan of treatment was established before (date of termination), payment may be made for up to 30 days after date of termination."

E. For Other Providers and Suppliers.--"The Medicare program will not make payment for (type of facility) services furnished to patients after the close of (date of termination)."

Arrange for publication of notice at least 15 days before the effective date of termination (2 days if immediate jeopardy), but not before the provider or supplier receives notice of termination.

In addition to preparation of legal advertisements, the RO may decide to develop and distribute a press release on the termination (or other action).

## 3036. BILLING FOR PUBLIC NOTICE OF TERMINATION OR WITHDRAWAL

A. Advertising Order, SF-1143.--Before arranging for publication of the termination notice, the RO/ARA obtains authorization from the RA via the Advertising Order, SF-1143 (Exhibit 184). The RO prepares an original and three copies, completing the front portion as shown in the exhibit. The RO attaches a copy of the text of the public notice to the original and to each copy of the SF-1143. After the RA signs the form (and retains one copy) the RO:

- o Types in the RO address in the bottom portion of the front of the SF-1143;
- o Sends the original and one copy to the newspaper. Inform the publisher that one of the following options should be used in claiming payment:
  - -- The back of the original SF-1143 may be completed with either a copy of the advertisement attached or a certification made in the space provided on the form; or
  - -- Any billing form may be submitted to the RA with a copy of the advertisement or a certification attached to the original SF-1143; and
- o Following publication of the public notice and upon receipt of the SF-1143 and attachments from the publisher, issues payment using funds available for this purpose.

## 3038. RESCINDING OR POSTPONING EFFECTIVE DATE OF TERMINATION

A. Initial Action.--The RO stops the processing of an involuntary termination if it is positively ascertained that the provider now complies with all requirements and that termination is no longer appropriate. The RO does not postpone a termination action for:

- o Meetings or visits with the provider;
- o CHOWs;
- o Court appointed receivership; or
- o Any other cause not explicitly required by statute, regulation, Federal court order, or procedures stated elsewhere in this chapter.

When credible evidence that the cause for the termination has been removed is received in time to halt publication of the public notice, the RO immediately contacts the newspaper to stop the scheduled notice and suspends the termination action pending RO and SA verification. If the termination action is later revived, the RO again makes arrangements for public notice.

When the RO receives credible evidence that the cause for the termination has been removed before the effective date of termination, it requests that the SA make a revisit as soon as possible or it conducts a Federal survey. The SA should make the revisit when:

- o The SA conducted the initial survey; or
- o Due to travel considerations, scheduling problems, or scarcity of resources, the RO has requested the SA to conduct the revisit, even though the RO conducted the initial survey.

The RO does not use allegations of compliance in the absence of credible evidence of compliance as the basis for postponing the effective date of termination.

B. Criteria For Credible Allegation.--A credible allegation must meet the following criteria:

- o The alleged corrective action should be detailed and must have removed the deficiency; and
- o The corrective action was of the kind that could have been accomplished between the survey date and the date of the allegation.

If the Medicare facility makes additional credible allegations of compliance following an earlier SA revisit, or between the 46th and 90th day prior to the effective date of termination, the SA will contact the RO for a determination as to whether a revisit will be made. Only two revisits are permitted, one before the 45-day period and one between the 46th and 90th day. The RO bases its determination on the validity and reasonableness of the evidence or documentation provided by the facility prior to conducting a revisit. A second or late revisit can be conducted by the SA only after RO approval.

C. Form of Public Notice of Termination Retraction For Providers.--

Notice is hereby given that (name and address of facility) has achieved compliance with the Medicare Conditions of Participation/Requirements for Participation pertaining to (CoPs or Requirements). As a result, the Secretary of Health and Human Services is continuing the agreement with (the facility) in the Medicare program.

D. Form of Public Notice of Termination Retraction For Suppliers.--(Optional at discretion of RO for suppliers other than RHCs, ASCs, and FQHCs.)

Notice is hereby given that (name and address of facility) has achieved compliance with the Medicare Conditions for Coverage pertaining to (Conditions of Coverage). As a result (the facility) will continue to participate in the Medicare program as a supplier of (type of supplier services).

## 3040. TERMINATING MEDICAID ICF/MR ELIGIBILITY BASED ON "LOOK BEHIND" DETERMINATION

Section 1910(b)(1) of the Act authorizes HCFA to terminate approval of a Medicaid ICF/MR's eligibility to participate in the Medicaid program when HCFA determines that the provider does not substantially meet the CoPs for ICFs/MR (42 CFR Part 483). The Act uses the terms "cancel" and "terminate" interchangeably. The adjudicative procedures are similar to those followed for terminating a §1866 provider agreement under §§3010 and 3012. Except in the case of immediate and serious threat situations, termination usually becomes effective after the provider has had an evidentiary hearing before an Administrative Law Judge (ALJ) and the ALJ has upheld the termination.

A. Termination Procedures.--

1. Immediate and Serious Threat.--At the exit conference, the RO team leader should explain the findings to facility management as well as which findings apparently constitute an immediate and serious threat to client health and safety. (See Appendix Q for examples.) The RO survey team leader explains that if his/her supervisor agrees with the seriousness of the team's onsite survey findings, the RO will notify the facility by electronic facsimile, telegram, or overnight express mail of the determination to cancel/terminate the facility's program participation unless the immediate threat is eliminated. The RO allows no more than 2 working days following the exit conference to determine whether circumstances found in the facility pose an immediate and serious threat to client health and safety and to notify the facility of your determination. The RO notifies the facility and SMA by electronic facsimile, telegram (Exhibit 185), or other expeditious means, that as a result of the finding that an immediate and serious threat to client health and safety exists, the it is initiating termination proceedings pursuant to §1910(b)(1). The RO telephones the SA to inform them of its determination. The RO gives the facility no more than 5 working days from the date of the notification to eliminate the threat and to notify it of the remedial action taken. Also,
state that if the facility does not notify the RO that the threat has been removed or compliance has been achieved by the time specified, it will assume the condition still exists and termination occurs on the proposed effective date.

If the threat is removed but deficiencies still exist at the Condition level, the RO uses the procedures for no immediate threat and give the provider up to 83 more days, or 90 days total (7 + 83) to correct the deficiencies.

Following HCFA termination based on immediate and serious threat, HCFA grants up to 30 days of Federal Financial Participation (FFP) for purposes of relocating patients after the effective date of termination. If an appeal is filed by the facility, the ALJ hearing is afforded after the effective date of termination and does not forestall termination from taking effect.

2. No Immediate Threat To Patients' Health and Safety.--If the ICF/MR is not in compliance with one or more of the CoPs, the RO completes the actions within the time limits prescribed.

a. Fifteenth Day.--The RO notifies the provider in writing of its deficiencies and that termination action is being initiated. Included in the notices is the provider's right to appeal this action, along with the effective date of termination. If the provider makes a credible allegation of compliance prior to the effective date of termination, the RO conducts a revisit. (See §3038.B.)

b. Seventieth Day.--The RO completes all related documentation. Notify the facility, the SMA, and the SA.

c. Ninetieth Day.--If compliance has not been achieved, the RO terminates participation.

If an appeal is filed by the facility, termination must be delayed pending the hearing and decision by the ALJ (see 42 CFR 498.5(j). The provider agreement remains in effect and FFP continues pending the appeal decision. If the facility makes a credible allegation of compliance during the appeal period, it is the RO's decision whether or not it is in the recipients' and the Federal Government's best interests to conduct a revisit and dispose of the case based on the findings. If a revisit is made and the facility failed to achieve compliance, adverse action continues based on the findings of the first Federal survey and the findings of the revisit. If at the time of the revisit the provider is in compliance with the requirements forming the basis for the original termination, but has new deficiencies which are also grounds for termination, the RO initiates a new termination process commencing with the revisit.

If the ALJ sustains the termination action, the effective date of termination and cessation of FFP is set by the ALJ. Further appeal by the facility to the DAB does not cause the provider agreement to be extended, i.e., payment does not continue pending a decision by the Departmental Appeals Board (DAB).

Whenever possible, the RO conducts the termination notification and decision making process in the 90-day timeframe used for Medicare terminations. However, there are circumstances that require that the RO gives a facility extra time. For example, with State-owned facilities, it sometimes takes longer to get a PoC because of the need for action by other parts of State government, thus requiring additional processing time. Keep these situations to an absolute minimum. In addition, an ALJ hearing may not be scheduled within the usual 90-day termination timeframe.

The reasonable assurance provisions apply to ICFs/MR terminated by HCFA.

## 3042. DISALLOWANCE OF FFP TO STATE BECAUSE STATE FAILS TO FOLLOW CORRECT CERTIFICATION PROCEDURES FOR MEDICAID PROVIDERS

This process applies when a SA or SMA has failed to properly apply Federal requirements or procedures in surveying or certifying a facility or in entering into a provider agreement, as described in 42 CFR s 442.30 and 431.610(g).

The "look behind" regulation (42 CFR 442.30) referred to as "old look behind" provides a mechanism for testing the validity of a provider agreement for FFP purposes. If certification procedures are not followed, HCFA does not accept the provider agreement between the State and the facility as evidence that the facility was properly certified. Whether a facility actually meets participation requirements is not the issue. The issue is that the State failed to adhere to Federal requirements in certifying and issuing an agreement to a facility. Therefore, HCFA will discontinue FFP to the State for the facility, even though payments were made prior to the RO determination. When the RO invokes this aspect of "look behind," it advises the SA and the SMA that the provider agreement cannot be accepted, and, for FFP purposes, the agreement is void from its inception.

If the SA failed to adhere to certification procedures, the RO requests additional information. The RO advises the agency that in the absence of a satisfactory response, the provider agreement is invalid for FFP purposes which will result in a disallowance of FFP for the period in question. The RO requests an explanation or evidence that would contravene a finding that Federal requirements were not followed. The nature of the issue (i.e., a defect in the survey versus a defect in the issuance of the provider agreement) determines whether the RO notifies the SA or the SMA. Whichever agency is notified, the RO sends copies of all correspondence to both agencies.

If unable to correct the difficulty through contact with the State, the RO contacts the Division of Medicaid regarding the problem. The RO recommends the disallowance of FFP for the State under the current provider agreement. A sample memorandum to the Medicaid Division is in Exhibit 186.

## 3044. TERMINATING APPROVAL FOR SUPPLIERS

If the SA certifies that a supplier is no longer in compliance with the Conditions for Coverage, the RO notifies the supplier of the certification and processes the termination. (See Exhibit 187.)

In supplier terminations, although there is no provider agreement to terminate and the Act does not use the term, "terminate," formal adjudicative disapproval is clearly implied in the Act. Unless otherwise noted, procedures for provider terminations are equally applicable to certified suppliers. SMAs are notified of supplier terminations. If the SMA continues making payments to Medicaid suppliers, FFP is disallowed. See Chapter VI for laboratories.

The termination of coverage is effective following at least a 2 day notice if immediate jeopardy is present, otherwise it is at least a 15 day notice to the supplier (42 CFR 489.53(c)).

The RO notifies the carrier and the Divisions of Medicare and Medicaid of a supplier termination action and the effective date.

Public notification is optional for suppliers other than RHCs, ASCs, and FQHCs. Public notification, when undertaken, should be given in accordance with §3034.

## 3046. VOLUNTARY TERMINATIONS

A. General.--Under the provisions of §1866(b)(1) of the Act, a provider of services may terminate its agreement by filing a written notice of its intention. If a Medicare provider/supplier notifies the SA of its desire to terminate its Medicare participation or if it ceases operations which is considered as voluntarily terminating its agreement, the SA notifies the RO immediately. The RO accepts the proposed termination date or set a different date. However, the termination date must not be more than 6 months from the date the notice is filed.

The RO determines the provider's or supplier's reason(s) for deciding to terminate participation. Identifying the reasons for voluntary termination aids in evaluating policies and procedures and focuses on problems not previously recognized.

1. Provider or Supplier Is Unable or Unwilling To Correct Deficiencies To Continue To Meet CoPs, Conditions For Coverage, or Participation Requirements for SNFs.--In many cases, the facilities have cited as a reason for seeking termination an inability to continue to meet the Conditions of Participation or Coverage or Requirements for participation for SNFs.

2. Provider Dissatisfied With Reimbursement.--If a provider is withdrawing because of disagreement with the reimbursement formula, the RO indicates this on Form HCFA-1539.

3. CHOW.--If, after a CHOW, the successor does not wish to participate, the date of termination is usually the date the previous owner ceased doing business. However, coverage of beneficiary services extends until it is learned that the successor will not continue operations under a provider agreement. Payment can continue for up to 30 days after a provider is terminated for hospitals, SNFs, HHAs and hospice beneficiaries who were admitted before the effective date of termination (42 CFR 489.55). (See §3008.)

4. Close of Business.--The provider may temporarily or permanently cease all business (Medicare and non-Medicare operations). No further RO action is necessary.

B. Decision By Provider or Supplier To Remain In Health Insurance Program.--If a provider or supplier changes its mind after requesting termination, the RO secures a written statement to document the provider/supplier file to prevent any future misunderstanding. If the voluntary termination has not already taken place, the RO sends a letter to the provider rescinding its voluntary termination. Copies are sent to the SA, SMA, the intermediary, and the carrier. If the provider's request is received after the effective date of the voluntary termination, the RO treats the request as an initial request to participate in the Medicare program.

C. Notice To Public.--In voluntary termination cases, the provider or supplier is obligated to notify the public of the effective termination date. An exception to the requirement for public notice is made when the RO receives retroactive notice of the close of a business. If the RO learns that the provider does not intend to comply with the requirement for a public notice, where required, the RO should assume the responsibility. The required public notice should be published

in the local newspaper with the widest circulation as soon as possible after the provider receives the RO's letter, and, if time permits, not less than 15 days before the effective termination date. When a supplier of services is voluntarily terminating program participation, public notice by either the supplier or the RO's office is optional. However, such a notice is to be published for RHCs, ASCs, and FQHCs.

D. Effective Date of Voluntary Termination.--The effective date of termination is the date business ceased (if there is closure) and should allow sufficient lead time to notify HCFA components and to give the public notice of the termination.. If the provider's request does not specify an acceptable termination date, the RO sets the date (42 CFR 489.52(b)). This date cannot be more than 6 months after the provider's request is dated. If a retroactive termination date is requested, the RO honors it, provided there were no Medicare beneficiaries receiving services from the facility on or after the requested termination date.

In setting an effective termination date which is less than 6 months in the future, the RO must be assured that it would not unduly disrupt the services to the community or otherwise interfere with the effective and efficient administration of the health insurance program. In making this determination, the RO considers the availability of other facilities in the area. In the case of a closure, the effective date is the actual date of closing.

## 3047. NOTICE TO INTERMEDIARY OR CARRIER - VOLUNTARY TERMINATION

The RO notifies the intermediary when it receives notice that a provider wants to terminate its participation. The RO keeps the intermediary informed of the status of the provider's request. This permits the intermediary to make preliminary arrangements for final cost reports and final settlement, and to adjust any outstanding payments to avoid overpayments in accordance with intermediary instructions. If a supplier is voluntarily terminated, the RO notifies the carrier immediately.

## 3048. NOTICE TO PROVIDER OR SUPPLIER - VOLUNTARY TERMINATION

A. Voluntary Termination.--Exhibits 188 and 189 may be used to notify the provider or supplier of approval of voluntary termination. The RO sends copies of the letter to the SA, intermediary or carrier, and, if appropriate, the SMA.

B. Close of Business.--The RO sends a letter modeled after Exhibit 190 to the provider with copies to the SA, intermediary, and, if appropriate, the SMA. If a supplier is closing, the RO notifies the carrier and sends a letter modeled after Exhibit 191.

## 3049. COMPLETING CERTIFICATION AND TRANSMITTAL (FORM HCFA-1539)

Voluntary Terminations and Close of Business.--In the upper left-hand corner The RO enters "VOLUNTARY TERMINATION--CODE 2."

The RO completes items 1, 3, 7, 26, 28, 29, 30 (signature of RO official delegated to sign), and 32.

Reconsideration, Hearings and Appeals

## 3050. INITIAL DETERMINATIONS VERSUS ADMINISTRATIVE ACTIONS - RIGHT TO REVIEW

Only initial determinations are subject to reconsideration, hearing, or appeal. In general, an initial determination is a decision with respect to the following matters:

- o Whether a provider or prospective provider meets or does not meet the Medicare requirements as a provider of services;

- o Whether a supplier or prospective supplier meets or does not meet the appropriate Conditions for Coverage of its services;

- o Whether the termination of a provider agreement or benefits agreement is in accordance with 42 CFR 489.53, the termination of a RHC agreement is in accordance with 42 CFR 405.2404, the termination of a FQHC agreement is in accordance with 42 CFR 405.2442, or the termination of an ASC is in accordance with 42 CFR 416.35;

- o Whether a hospital meets or does not meet or continue to meet the requirements to qualify as an emergency services hospital;

- o Whether the services of a supplier meet or continue to meet the Conditions for Coverage; or

- o The effective date of the provider agreement between HCFA and a provider of services, or the effective date HCFA approved for a supplier of services.

## 3052. NATURE OF RECONSIDERATION DETERMINATION -- SA PROCEDURES

A. Right to Reconsideration of Initial Denial.--Reconsideration is granted administratively, not statutorily, pursuant to regulations 42 CFR Part 498.22 through 498.25. Any prospective provider or supplier dissatisfied with an initial determination that does not qualify as a Medicare provider may submit a request that the Secretary reconsider the decision within 60 days from receipt of the notice of initial determination.

Reconsideration is a review of the determination. This review results in affirmation or reversal or the determination. Further appeal rights include hearing before an ALJ and review by the DAB.

B. Request for Reconsideration.--A request for reconsideration is any written expression of dissatisfaction with the initial decision. The request may be in the form of a letter or statement that explains the issues, or the findings of fact with which the affected party disagrees, and the reasons for the disagreement. The reconsideration request may be signed by any responsible official of the provider or by an attorney on behalf of the provider. The SA officially dates or date-stamps any request the day of receipt in the SA.

C. Acknowledgement of Reconsideration Request.--The SA acknowledges the request promptly and forwards a copy of the request and acknowledgement letter to the RO immediately. The RO will advise if additional development is required. Also, the SA forwards any subsequent information received that would affect the reconsideration or hearing. If the request is filed by an attorney, the SA sends a copy of the acknowledgement to the provider. Most cases require SA redevelopment, particularly if there are questions about the provider's efforts and plans to correct previously cited deficiencies. If requesting additional evidence from the entity, stipulate in the acknowledgement a reasonable deadline for submittal.

D. Documentation of File.--A reconsideration review is not complete unless the file contains adequate documentation to fully explain every statutory deficiency and finding of noncompliance with program requirements. The SA sends the RO all reports of on-site visits and telephone contacts with the provider, as well as any pertinent information available form the licensing agency.

## 3054. RECONSIDERATION -- RO PROCEDURES

A. Review.--A reconsideration is a thorough, independent review of the prior decision and entire body of evidence, including any new information developed. If the facility has made corrections since the survey on which the original determination was based and the SA can verify this, the provider may no longer wish ot pursue its recommendation request in lieu of accepting certification based on the date of compliance with all Conditions or substantial compliance with Requirements for SNFs.

A reconsideration review if not complete unless and until every adverse finding (i.e., does not meet one or more statutory requirement, is not in substantial compliance with one or more CoPs) is adequately documented.

B. RO Receipt of Request.--A provider or supplier of services which has been denied participation may file a request for reconsideration in any manner through any HCFA RO, SA, or intermediary. The request may be in the form of a letter or statement and may be signed by any responsible official of the provider/supplier, or by an attorney on behalf of the provider. The RO officially dates or date-stamps any request the day of receipt in the RO. The request for reconsideration must state the issues or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

C. Acknowledgement or Reconsideration Request.--The RO acknowledges reconsideration requests within 3 days of receipt. If the request is filed by an attorney, the RO sends a copy of the acknowledgement to the facility. If there is an offer to submit additional evidence or if the RO requests additional information, a reasonable deadline for its submittal is provided in the acknowledgment. The RO informs the facility that the SA may be in touch to obtain additional information. The RO informs the SA that the facility has requested reconsideration.

D. Reconsideration Determination.--The RO completes a Certification and Transmittal, Form HCFA-1539, except for Items 17 and 18 if the original determination is reversed. The RO marks the top of all copies of the form "Reconsideration - (Affirmed) or (Reversed)" and distribute the copies as in an initial decision. The RO does not need to complete Form HCFA-1539 if the SA has made a revisit and the certification is based on the revisit. The SA in this case will complete Form HCFA-1539. If OCR clearance has not yet been received, the RO advises OCR that a previously denied facility has now been approved so that they may complete the clearance process. The RO sends two copies of the Provider Agreement and Statement of Financial Solvency, HCFA-2572, to the entity for completion. The cover letter should request immediate return of the forms and point out that a final determination has not been made on the request for reconsideration. If any title VI forms are needed, these are sent with the agreement forms.

E. RO Notice of Reconsidered Determination.--

1. Denial Reversal (Approval).--The RO confirms civil rights compliance before revising a denial of a provider on reconsideration. If the provider is not in compliance, see §2010.

After confirming that other documentation such as the Statement of Financial Solvency, Form HCFA-2572, is in order, the RO assigns a provider identification number and completes a Certification and Transmittal, Form HCFA-1539, marking item 30, "Reconsideration Reversed."

The RO issues a notice of acceptance as in a routine initial approval, enclosing the countersigned provider agreement. The notice of acceptance should reflect that the determination was reconsidered.

The RO notifies the SA of the revised decision and sends a Provider Tie-In Notice, Form HCFA-2007, to the intermediary.

2. Denial Affirmed.--With the notice of decision, the RO includes a listing of each CoP, Condition for Coverage, or Requirement for SNFs with which the facility is not in compliance (for SNFs, substantial compliance). The RO includes a detailed explanation of why the deficiencies result in a determination and decision that the facility is not in compliance (substantial compliance for SNFs), the provider's efforts and plans to correct deficiencies notwithstanding. The notice advises the facility of its rights to a hearing if it files a request within 60 days of the date of receipt of the reconsideration decision of denial. The RO advises the facility to send the hearing request to it, Attn: ARA, HCFA. The RO forward all requests for hearings to the DAB for further action. The RO keeps a copy of the notice in the provider file and sends a copy to the SA. The RO acknowledges the receipt of the facility's request for hearing in writing (see Exhibit 192).

3. Acting Official For Reconsideration Denial Notices.--If a reconsideration request is denied, the reviewer who was assigned the initial determination should not sign the denial notices at the reconsideration level.

o Initial Denial NOT Signed By ARA.--If the ARA did not sign the initial denial notice, he/she should sign the reconsideration denial notice.

o Initial Denial Signed By ARA.--If the ARA- signed the original notification of denial, forward the file and formal recommendation to the RA. The notice of reconsideration denial is released over the RA's signature. The RO notifies all interested components and prepares and transmits the required Form HCFA-1539.

o Problem Cases Needing CO Review.--If the reconsideration action presents policy issues or problems that in the RO's judgment need resolution, send the case to the CO with a statement of the problem and request guidance.

The RO prepares and transmits Form HCFA-1539 and adjudicative notices to the SMA, SA, and intermediary.

## 3056. RO REVIEW PROCESS OF ALJ ADVERSARIAL HEARING DECISIONS

For purposes of this section, adversarial hearing cases are those in which HCFA is a party in the dispute, and where the decisions involve provider/supplier appeals of initial, revised initial, reconsidered, or revised reconsidered determinations. (See 42 CFR 498.5.) An affected party dissatisfied with any one of these determinations may file a request for hearing with the RO. The RO advises the party to address the request to the attention of the ARA, HCFA. The RO forwards all requests for hearings to the DAB for further action. All ALJ decisions originate in DAB and are then forwarded to the RO directly or via the regional General Counsel. The RO should contact these offices on a routine basis to ensure that it receives all current information on pending cases.

The RO establishes and maintains a control/tracking system for assembling, reviewing, and analyzing all relevant documents. The RO retains any factual information (e.g., survey information, allegations, testimony, follow-ups) associated with the ALJ case prior to and following the hearing proceedings. This documentation will be used to track the case through various stages of development.

Upon receipt of the ALJ decision, the RO reviews it and prepares a report (see subsection C) briefly summarizing the case and the ALJ decision. The report should be no more than a couple of pages, indicating requested information in bullet point format. The RO forwards both a copy of the decision and its report to CO within 30 days from the date it receives the decision.

The RO control/tracking evaluation process for ALJ decisions must provide for:

A. Case Control Number.--Assign a unique identifying case control number to each case as follows:

o Begin the control number with the current two-digit fiscal year designation (e.g., 1988=88, 1989=89);

o The next series of numbers includes the six-digit provider number or ten digit supplier number (as applicable), (e.g., 215000, 21L0000001); and

o The last series of numbers consists of a consecutive numerical designation in chronological order by decision date, beginning with one for each fiscal year. Maintain sequential numbering series within each region.

B. Evaluation.--Evaluate each decision to determine if:

o There exists any significant strengths and/or weaknesses in the case (especially those points attributed to HCFA's win or loss); and/or

o The decision affects HCFA policy, procedures and/or regulations.

C. Preparation of Report.--After evaluating the case, the RO prepares a report, briefly addressing all of the following:

o Issue(s) challenged by the provider/supplier (i.e., specific initial, revised initial, reconsidered, or revised reconsidered determinations and related findings);

o HCFA's position in the case (brief explanation of the facts, along with HCFA's interpretation of requirements);

o ALJ decision (i.e., affirmation, reversal, or partial reversal);

o Briefly state why an ALJ decision resulted in reversal or partial reversal (if applicable); and

o Recommendations resulting from the decision (e.g., procedures and/or policy changes).

NOTE: Where the decisions have overturned HCFA initial, revised initial, reconsidered, or revised reconsidered determinations, the RO consults with the Regional Office of the General Counsel before submitting recommendations to CO.

## 3058. HEARING ON §1910(b) CANCELLATION OF MEDICAID ELIGIBILITY

If a hearing is requested on a termination of an ICF/MR's Medicaid participation by HCFA, send the provider's request for a hearing to the DAB.

## 3060. APPEALS OF ADVERSE ACTIONS FOR MEDICAID NON-STATE OPERATED NFs (NON-STATE OPERATED) AND ICFs/MR (NOT APPLICABLE TO FEDERAL TERMINATIONS OF MEDICAID FACILITIES)

Denials, terminations, cancellations, and denials of payment for new admissions and other adverse actions to facilities participating in Medicaid-only are State administrative actions and decisions.

State appeal procedures must be made available to facilities in cases of nonrenewal, denial, cancellation, or termination of the provider agreement. It is up to the State to designate the office or official having authority to hear and decide Medicaid appeals. Although the State retains considerable flexibility in developing its own appeal procedures, the procedures for an ICF/MR must at a minimum provide for an evidentiary hearing either before or within 120 days after the effective date of the adverse action. The State must also provide an informal reconsideration prior to taking adverse action if it elects to provide a full evidentiary hearing after the effective date of the adverse action for an ICF/MR (42 CFR s 431.150 through 431.154).

If a NF requests a hearing on a denial or termination of its provider agreement, the request does not delay the adverse action and the hearing need not be ocmpleted before the effective date of the action. However, a NF is entitled to a hearing before a CMP is collected (see §7526).

NOTE: In the procedures for denial of payment for new admissions for ICFs/MR (see subsection C), a post-termination hearing is not a permitted option. The State must provide an informal hearing before the effective date of the denial of payments for new admissions. Consequently, reconsideration is not appropriate for these appeals.

A. Informal Reconsideration.--The State may develop and implement its own reconsideration proceedings. However, the process must include:

- Timely notice of the reason for the action;
- A reasonable opportunity for the facility to refute those reasons in writing; and
- A written decision prior to the effective date of the adverse action.

B. Evidentiary Hearing.--The evidentiary hearing must include:

- Timely written notice to the facility of the findings upon which the termination or denial is based, and disclosure of the evidence on which the decision is taken;
- An opportunity for the facility to appear before an impartial decision maker to refute the basis for the decision;
- An opportunity for the facility to be represented by counsel or another representative;
- An opportunity for the facility or its representatives to be heard in person, to call witnesses, and to present documentary evidence;
- An opportunity for the facility to cross-examine witnesses; and
- A written decision by an impartial decision-maker, setting forth the reasons for the decision and the evidence on which the decision is based.

C. Informal Reconsideration (Applies to ICFs/MR FOR Denial of Payment For New Admissions Only).--The informal hearing process must include:

- Timely notice of the reason for the action;
- A reasonable opportunity for the facility to present in writing or in person reasons for its disagreement;
- An opportunity for the facility or its representatives to be heard in person and to present documentation; and
- A written decision by an impartial decision maker, prior to the effective date of the denial of payment, setting forth the reasons for the determination. The informal hearing is not followed by an evidentiary hearing.

D. Judicial Review.--Federal regulations do not provide for judicial review of these appeals proceedings. Judicial review is governed by State law.

E. Impartial Decision Maker (Hearing Officer).--The State has flexibility in selecting individuals to conduct the reconsideration and hearing proceedings. However, in both proceedings, certain individuals should be excluded from serving as decision makers.

In reconsideration proceedings, the SA as well as other persons directly involved in gathering and providing evidence upon which the adverse action is based, are ineligible to make decisions. (One person should not be both witness and judge.) However, the person who made the original determination based on the surveyors' findings is not ineligible to decide the reconsideration. If the decision is originally made at the highest level, the appeal decision should also be made there. However, if the original decision is made by a regional supervisor, have someone higher in authority review the appeal.

In administrative hearings, all persons directly involved in either the survey or the reconsideration process are ineligible for reasons of impartiality.

Prospective Payment System (PPS)

## 3100. HOSPITALS AND HOSPITAL UNITS EXCLUDED FROM PPS - ANNUAL SELF-ATTESTATION

A limited group of hospitals and special hospital units are excluded from PPS which determines Medicare payment for operating costs and capital-related costs of inpatient hospital services. 42 CFR s 412.20 through 412.30 describes the criteria under which these facilities are excluded. Excluded hospitals and units are paid on the basis of reasonable costs subject to target rate ceilings (provided for by §1886(b) of the Act.) PPS-excluded status is not optional. In the past, the SAs have been required to conduct annual onsite surveys of these hospitals and units to verify that they continue to meet certain PPS-exclusion criteria. This procedure is revised as follows:

- Annual on-site verification surveys for rehabilitation hospitals and units, and psychiatric units are no longer required, and these PPS-excluded hospitals/units may now self-attest, on an annual basis, that they continue to meet PPS-exclusion criteria;

- Previously excluded hospitals/units are required to report any change in operations (e.g., expansion or downsizing) to the appropriate HCFA RO, and to provide the SA with a copy of the report within 10 days after the change occurs;

- The SA conducts annual validation compliance surveys of a five percent sample of all currently excluded hospitals/units drawn at random;

- The SA continues to conduct complaint surveys at excluded hospitals/units; and

- The SA continues to conduct certification surveys for first-time PPS exclusion for hospitals and units.

FIs continue to verify, on an annual basis, compliance with the 75 percent rule for rehabilitation hospitals and units (42 CFR Part 412.23 and 412.30); age criterion for children's hospitals (42 CFR 412.23(d)(2)); length of stay criterion for long-term hospitals (42 CFR 412.23(e)(2); and the requirement that all excluded units are separate cost centers for cost finding and apportionment (42 CFR 412.29(a)(9)).

## 3102. GENERAL INFORMATION ON PPS EXCLUSION

The following hospitals and hospital units are excluded from PPS:

- Psychiatric hospitals;

- Rehabilitation hospitals;

- Children's hospitals;

- Long-term hospitals;

- Distinct part psychiatric and rehabilitation units of general acute care hospitals that are subject to PPS; and

- Cancer hospitals.

Certain kinds of hospitals are paid under special provisions and are never subject to PPS. These hospitals need not be evaluated for compliance with the PPS exclusion criteria:

- Department of Veterans Affairs (formerly, Veterans Administration) hospitals;
- Hospitals paid under State cost control systems approved by HCFA;
- Hospitals paid under demonstration projects approved by HCFA;
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries; and
- Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.

When a hospital is excluded from PPS, the exclusion extends to all components of the hospital. No unit or other component of an excluded hospital can be considered separately for exclusion. However, if a medical-surgical facility is located in the same building as a psychiatric hospital, but participates separately in Medicare as a hospital, it is not considered part of the psychiatric hospital and is not excluded based on the exclusion of the psychiatric hospital.

However, the only hospital units that have ever been certified as separate hospitals are medical-surgical units of psychiatric hospitals. (See §2050.) A medical-surgical unit that participates as a separate hospital is assigned a separate provider number in which the last four digits are between 0001 and 0899, inclusive. HCFA applies the criteria for PPS exclusion independently to any separately certified medical-surgical unit even though it is located in an excluded psychiatric hospital.

Hospitals (except those now certified as psychiatric hospitals) and hospitals containing units meeting the criteria of §3106 (based on the hospital's self-identification) are to notify the RO that they qualify. Such notification includes the following: name of hospital, type of hospital/unit(s), address, current provider identification number, name of contact person, FI and a statement that the hospital/unit meets the criteria for exclusion. A notice relating to a unit is to identify the particular areas designated as the unit and specify the number of beds and square footage included in the unit. Room numbers or the number of beds must be used to identify the designated space. When possible, the notification is to be made no later than 5 months before the date the hospital would otherwise become subject to prospective payment. After receipt of this notification, the RO asks the SAs to verify that certain criteria are met for psychiatric units of general hospitals, for rehabilitation hospitals and rehabilitation units of general hospitals.

Excluded or nonexcluded status for a hospital or hospital unit remains in effect for the entire cost reporting period for which the determination is made. If a change in meeting applicable criteria occurs during a cost reporting period, or the hospital requests PPS exclusion after the start of its cost reporting period, the status determined for that period remains for the duration of the period. For purposes of exclusion, increases or decreases in the number of beds and square footage assigned to a PPS excluded unit are recognized only at the start of a hospital's cost reporting period.

If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from PPS before the start of the hospital's next cost reporting period.

## 3104. CRITERIA FOR PPS-EXCLUDED HOSPITALS

A. Psychiatric Hospitals.--A hospital certified as a psychiatric hospital under existing requirements is excluded.

B. Rehabilitation Hospitals.--A hospital is an excluded rehabilitation hospital if:

o It has in effect a provider agreement to participate as a hospital;

o During its most recent 12-month cost reporting period it treated an inpatient population of which at least 75 percent required intensive rehabilitative services for one or more of the following conditions:

- Stroke;
- Spinal cord injury;
- Congenital deformity;
- Amputation;
- Major multiple trauma;
- Fracture of femur (hip fracture);
- Brain injury;
- Polyarthritis, including rheumatoid arthritis;
- Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease; or
- Burns.

o It has in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital rehabilitation program or assessment;

o It ensures that patients receive close medical supervision, rehabilitation nursing, physical therapy, and occupational therapy plus, as needed, speech therapy, social services or psychological services, and orthotic and prosthetic services;

o It has for each inpatient, a plan of treatment that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient;

o It uses a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries to the patient's medical record noting the patient's status in relationship to goal attainment, and team conferences are held at least every 2 weeks to determine the appropriateness of treatment; and

o It has a director of rehabilitation who:

- Provides services to the hospital and its inpatients on a full-time basis;
- Is a Doctor of Medicine or Osteopathy licensed under State law to practice medicine or surgery; and

- Has had, after completing a 1-year hospital internship, at least 2 years of training in the medical management of inpatients requiring rehabilitation services.

For purposes of determining whether the 75 percent rule is met, the SA considers the medical condition of all patients (i.e., Medicare and non-Medicare) treated in the hospital. The SA uses either the number of admissions or the number of discharges during a cost reporting period. Do not use the number of patient days of care.

The 75 percent rule is applied to the 12-month cost reporting period immediately preceding the cost reporting period for which exclusion is sought. The cost reporting period need not be complete when this evaluation takes place. The RO requests the servicing intermediary to make the determination concerning the 75 percent rule.

ALTERNATIVE: A hospital that seeks exclusion as a rehabilitation hospital for the first full l2-month cost reporting period that occurs after it becomes a Medicare participating hospital could not possibly meet the usual rule above, so a first-time exception to the rule is provided the hospital if it provides a written certification that the inpatient population it intends to serve will meet the 75 percent rule.

The written certification described above is effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period. This exception is available only once, when the facility first gains excluded status.

If a new rehabilitation hospital is excluded from PPS for a cost reporting period, but the inpatient population treated in the hospital during the period does not actually meet the 75 percent rule, a retroactive adjustment of payments to the hospital for the period is needed. Where this occurs, the SA advises the RO of the identity of the hospital and of the dates of the cost reporting period involved.

C. Children's Hospitals.--A hospital is an excluded children's hospital if it has in effect an agreement to participate as a hospital, and more than 50 percent of its inpatients are individuals under the age of 18. The servicing intermediary verifies compliance.

D. Long-Term Hospitals.--A hospital is an excluded long-term hospital if it has in effect a provider agreement to participate as a hospital and the average inpatient length of stay is greater than 25 days. The average length of stay, for this purpose, is determined by dividing the total number of inpatient days for all patients (excluding leave of absence or pass days) by the total number of discharges for the cost period. The servicing intermediary verifies whether rehabilitation hospitals meet this length of stay criterion as long-term hospitals, and are, therefore, eligible for a
long-term hospital exclusion and do not have to meet the special criteria otherwise established for these categories of facilities. The servicing intermediary verifies length of stay for all long-term hospitals.

Long-term hospitals that occupy space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital (i.e., the host facility), must meet additional "hospital-within-a-hospital" criteria at 42 CFR 412.23(e)(3) as follows:

o The hospital has a governing body that is separate from the governing body occupying space in the same building or campus, and the governing body is not controlled by the host facility or any third entity that controls both hospitals;

o The hospital has a chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of the hospital, and is not employed or under contract with the host facility or any third party that controls both hospitals;

o The hospital has a separate medical staff from the medical staff of the host facility, reports directly to the hospital's governing body, and adopts and enforces bylaws governing medical care provided in the hospital and medical staff activities, including the granting of privileges to individual practitioners;

o The hospital has a single chief executive officer through whom all administrative auhority flows and who exercises control and surveillance over all administrative activities at the hospital, and who is not employed by or under contract to the host facility or any third party who controls both hospitals; and

o The hospital meets one of the following criteria:

- The hospital performs the basic hospital functions (i.e., quality assurance, nursing services, medical records services, pharmaceutical services, radiologic services, laboratory services, utilization review, and infection control) using its own employees or under contracts or other arrangements with entities other than the host facility or any third party that controls both entities;

- Services obtained by the hospital under contracts or arrangements with the host facility or a third party entity that controls both hospitals do not exceed more than 15 percent of its total inpatient operating costs during the six-month qualifying period described in §3104D; or

- At least 75 percent of the hospital's inpatient population, during the six-month qualifying period described in §3104D, were referred from a source other than the host facility.

The SA notifies the HCFA RO as soon as it becomes aware of any long-term hospital planning to operate as a "hospital-within-a-hospital," and notify the facility immediately that it must demonstrate compliance with the special "hospital-within-a-hospital" criteria in §3104D in order to be approved as a PPS-excluded long-term hospital. The RO requests the facility to provide its office with all necessary documentation to allow it to make a recommendation to the RO regarding its compliance with these criteria. In some instances, the RO may require an on-site inspection of the facility in order to make a final determination.

## 3106. CRITERIA FOR PSYCHIATRIC AND REHABILITATION UNITS

A PPS-excluded psychiatric unit must meet both the general criteria for units and the specific criteria for psychiatric units below. A PPS-excluded rehabilitation unit must also meet the general criteria for units and the specific criteria for rehabilitation units below.

A. General Criteria for Units.

o The unit is a part of an institution that:

- Has in effect a provider agreement to participate as a hospital;

- Is not excluded in its entirety from PPS; and

- Has enough beds not excluded from PPS to permit the provision of adequate cost information.

o The unit has written admission criteria applied uniformly to both Medicare and non-Medicare patients;

o The unit has admission and discharge records that are identified separately from those of the hospital in which it is located, and that are readily retrievable. The medical records of the unit's patients need not be physically separate from the records of patients in the acute care portion of the hospital. It is not necessary to create a second medical record when a patient is moved from the acute care portion of the hospital to the excluded unit or vice versa. The record, however, must indicate, for Medicare purposes, the dates of admission and discharge from the excluded unit. The unit's policies provide that necessary clinical information accompany a patient upon transfer from the hospital to the unit;

o If State law provides special licensing requirements for psychiatric or rehabilitation units, the unit is licensed in accordance with the applicable requirements;

o The hospital's UR plan includes specific standards for the type of care offered by the unit;

o The beds assigned to the unit are physically separate from (not commingled with) beds not included in the unit;

The unit must also meet the accounting requirements set forth in §§2803.B.1.g through j of the Provider Reimbursement Manual. These include requirements that:

o The unit is treated as a separate cost center for cost finding and apportionment purposes;

o The hospital's accounting system properly allocates costs attributable to the unit and maintains statistical data that are adequate to support the basis of allocation of shared costs;

o The cost report for the hospital includes the costs of the unit in the same fiscal period and uses a single method of cost apportionment;

o As of the first day of the first reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed, and capable of providing inpatient psychiatric or rehabilitation care, regardless of whether there are any inpatients in the unit on that date; and

o Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from PPS.

B. Specific Criteria For Psychiatric Units.--A SA on-site verification or reverification survey for PPS exclusion of a psychiatric unit is required for a hospital filing a first-time request for PPS exclusion for its psychiatric unit, a psychiatric unit that has been selected as part of a sample for an annual validation survey, and/or a complaint against a psychiatric unit. For cost reporting periods following the first cost reporting period, the hospital is to self-attest that its psychiatric unit is in compliance with the requirements at 42 CFR Part 412.27.

1. Patient Criteria.--The unit admits only patients requiring admission for active treatment, of an intensity that can be provided only in an inpatient hospital setting. The psychiatric principal diagnosis must be one contained in the Third Edition of the American Psychiatric Association Diagnostic and Statistical Manual, or in Chapter 5 ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM);

2. Services Provided.--The unit furnishes, through the use of qualified personnel, psychological, social work, psychiatric nursing, occupational and recreational therapy services; and

3. Medical Records.--The unit maintains medical records that permit determination of the degree and intensity of treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

a. Development of Assessment/Diagnostic Date.--The medical record stresses psychiatric findings in the history, physical examination findings and treatment plan. It also includes the doctor's orders for the psychiatric condition for which the patient is treated.

o The identification data includes the inpatient's legal status (i.e., court commitment or voluntary admission);

o A provisional or admitting diagnosis is made at the time of admission. The record also includes the diagnoses of intercurrent diseases as well as psychiatric diagnoses;

o The reasons for admission are clearly documented as stated by the patient or others significantly involved, or both;

o The social service record, including reports of interviews with patients, family members, and others provides an assessment of home plans and family attitudes, community resource contacts and a social history; and

o When indicated, a complete neurological examination is recorded at the time of the admission physical examination.

b. Psychiatric Evaluation.--Each patient receives a psychiatric evaluation that:

o Is completed within 60 hours of admission;

o Includes a medical history;

o Contains a record of mental status;

o Notes the onset of illness and the circumstances leading to admission;

o Describes attitudes and behavior;

o Estimates intellectual functioning, memory functioning, and orientation; and

o Includes an inventory of the patient's assets in descriptive, not interpretive, fashion.

c. Treatment Plan.--

o Each patient has a comprehensive treatment plan based on an inventory of his/her strengths and disabilities; and

o The written plan includes:

- A substantiated diagnosis,

- Short-term and long-term goals,

- The specific treatment modalities,
- The responsibilities of each member of the treatment team, and
- Documentation which justifies the diagnosis and treatment and all active therapeutic efforts.

d. Progress Notes.--Physician progress notes must be documented by a Doctor of Medicine or Osteopathy responsible for the care of the patient, a nurse, a social worker and, when appropriate, others significantly involved in active treatment modalities. Progress notes frequency are based on the condition of the patient, but they must be recorded at least weekly for the first 2 months, and at least monthly thereafter. They should contain recommendations for revisions in the treatment plan as indicated, as well as a precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.

e. Discharge Planning and Discharge Summary.--The record of each discharged patient has a discharge summary that must include a recapitulation of the patient's hospitalization in the unit, recommendations from appropriate services concerning follow-up or aftercare, and a brief summary of the patient's condition on discharge.

4. Staffing.--The unit meets special staff requirements and has adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:

a. Personnel.--The unit employs or undertakes to provide adequate numbers of qualified professional, technical, and consultative personnel to:

- o Evaluate patients;
- o Formulate written individualized comprehensive treatment plans;
- o Provide active treatment measures; and
- o Engage in discharge planning.

b. Director of Inpatient Psychiatric Services and Medical Staff. The number and qualifications of Doctors of Medicine and Osteopathy are adequate to provide essential psychiatric services.

Inpatient psychiatric services are under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program and who:

- o Meets the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry, and
- o Monitors and evaluates the quality and appropriateness of services and treatment provided by the medical staff.

In verifying the training and experience requirements of the clinical director, the SA follows the Hospital Interpretive Guidelines and survey procedures specified in Appendix A. (See 42 CFR 482.62(b)(1).) A director is qualified to take the examination for board certification upon successful completion of a psychiatric residency program approved by either of the two boards.

c. Nursing Services.--The unit has a qualified director of psychiatric nursing services. There are also adequate numbers of RNs, LPNs, and mental health workers to provide care necessary under each patient's active treatment program and to maintain progress notes on each patient.

The director of psychiatric nursing services is an RN who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or is qualified by education and experience in the care of the mentally ill. The director demonstrates competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

The staffing pattern ensures the availability of a registered nurse 24 hours each day. There are adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

d. Psychological Services.--The unit provides or has available psychological services to meet the needs of the patients. The services are furnished in accordance with accepted standards of practice and established policies and procedures.

e. Social Services.--There is a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services are furnished in accordance with accepted standards of practice and established policies and procedures.

Social service staff responsibilities include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

f. Therapeutic Activities.--The unit provides a therapeutic activities program. The program is appropriate to the needs and interest of patients and is directed toward restoring and maintaining optimal levels of physical and psychosocial functioning. The number of qualified therapists, support personnel, and consultants are adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

C. Specific Criteria For Rehabilitation Units.--A SA onsite verification or reverification survey for PPS exclusion for a rehabilitation unit is to be performed for a hospital's first-time request for PPS exclusion for its rehabilitation unit, a rehabilitation unit that is selected as part of a sample for an annual validation compliance survey, and/or a complaint against a rehabilitation unit. For cost reporting periods following the first cost reporting period, the hospital will self-attest that its rehabilitation unit is in compliance with the requirements in 42 CFR 412.29.

The unit meets the requirement in §3104.B., except as provided below, with respect to patients treated in the unit during the hospital's most recent 12-month cost reporting period, i.e., the period immediately preceding the period for which the exclusion would be effective. This finding is based on the medical conditions of all (i.e., Medicare and non-Medicare) patients who occupy the beds assigned to the physically separate unit. The medical condition of all patients treated in the unit is considered.

If a hospital has not previously sought exclusion for any rehabilitation unit, and has both increased its bed capacity under Medicare certification and obtained approval for added bed capacity under State licensure, it may identify the new beds as a new rehabilitation unit for the first full 12-month cost reporting period during which the unit is in service. For purposes of these provisions, "new beds" are defined as ones for which the hospital has obtained approval by increasing its bed capacity under both State licensure and Medicare certification. Note that there is no net increase if the

hospital adds 20 new beds and deletes 20 beds previously licensed and certified for conversion. A unit that is comprised of some beds that were previously licensed and certified, and some new beds, will be recognized as a new rehabilitation unit only if over half of the beds are new. Beds are considered "new" only for the first full 12-month cost reporting period in which a hospital seeks exclusion of a new rehabilitation unit. The hospital may provide written certification that the inpatient population it intends the unit to serve meets the 75 percent rule instead of showing that it has treated such a population during its most recent 12-month cost reporting period.

The hospital that has an excluded rehabilitation unit must obtain approval for added bed capacity under State licensure requirements. If the hospital seeks to add the new beds to its existing excluded unit for the first full 12-month cost reporting period during which the new beds are used to furnish inpatient care, it must provide written certification that the new beds are intended to meet the 75 percent rule (see §3104.B) instead of showing that those beds were used to treat such a population during the unit's most recent 12-month cost reporting period.

The written certification described above is effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period. For purposes of this exclusion, a hospital that has undergone a change of ownership or leasing (see §3210) is not considered to have participated previously in the Medicare program.

If a hospital has a new rehabilitation unit excluded from PPS for a cost reporting period, or expands an existing PPS-excluded rehabilitation unit through the addition of new beds as defined above, but the inpatient population treated in the new unit of added beds during the period does not actually meet the 75 percent rule, a retroactive adjustment of payments to the hospital for the period is needed. Where this occurs, the SA advises the RO of the identity of the hospital and the dates of the cost reporting period involved.

If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare participating hospital. The written certification described above also is effective for any cost reporting period of not less than one month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period. For purposes of this exclusion, a hospital that has undergone a change of ownership or leasing (see §3210) is not considered to have participated previously in the Medicare program.

- The unit meets the requirements for a rehabilitation hospital in §3104. (The intermediary verifies the 75 percent rule.)

- The unit has a director of rehabilitation who:

  - Is a Doctor of Medicine or Osteopathy licensed under State law to practice medicine or surgery;

  - Has had, after completing a 1-year hospital internship, at least 2 years of training or experience in the medical management of inpatients requiring rehabilitation services; and

  - Provides services to the unit and its inpatients for at least 20 hours per week.

If the rehabilitation unit serves both inpatients and outpatients through a single, integrated unit, the time spent by the director in performing administrative duties for the entire unit counts toward the time requirement. The SA does not prorate this administrative time between inpatients and outpatients. However, time devoted to performing direct patient care can count toward the time requirement only if furnished to inpatients of the unit.

## 3108. SA FIRST-TIME VERIFICATION PROCEDURES FOR HOSPITALS AND UNITS

At the time the SA is requested to verify PPS exclusion of a rehabilitation hospital, or a psychiatric or rehabilitation unit of a hospital for the first time, it completes the appropriate part of the Criteria Worksheet, Form HCFA-437, 437A or 437B (Exhibit 73). The SA verifies that the criteria specified below are met for exclusions of hospitals and units of hospitals. In addition, the RO may instruct the SA to verify some or all of the general criteria for units given in §3106A.

A. Rehabilitation Hospitals and Rehabilitation Units of Hospitals.--

1. Rehabilitation Hospitals.--The SA verifies that the criteria in §3104B are met. (The intermediary verifies the 75 percent rule.)

2. Rehabilitation Units.--The SA verifies that the criteria in §3106C are met. (The intermediary verifies the 75 percent rule.)

3. Criteria Presumed Met by Accredited Rehabilitation Hospitals and Units.--A rehabilitation hospital or unit may be presumed to meet the criteria in §3104.B or §3106.C (excluding the 75 percent rule and the director requirement) if it is accredited by:

- Commission on Accreditation of Rehabilitation Facilities (CARF), surveyed under the Comprehensive Inpatient Rehabilitation (CIRP) Program; or

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Hospitals/units surveyed under the Joint Commission Comprehensive Physical Rehabilitation Program or Unit include the provisions of standard RH.3 in the Joint Commission Accreditation Manual for Hospitals.

Nevertheless, in either case, the SA verifies that the criterion for full-time director for rehabilitation hospitals or the 20 hour per week criterion for the rehabilitation unit is met. The SA reviews appropriate documentation submitted by the facility (e.g., payroll records, duty rosters, staff appointment notice specifying either full-time or part-time appointment of at least 20 hours per week).

B. Psychiatric Units of Hospitals.--The SA verifies that the criteria in §3106 are met.

The SA schedules an onsite verification visit at least 90 days prior to the end of the hospital's cost reporting period. The SA records the survey findings using the applicable section of the Criteria Worksheet, Form HCFA-437 and transmits the worksheet to the RO at least 60 days prior to the end of the hospital's cost reporting period for inclusion with other information necessary for determining exclusion from PPS.

For a first-time verification survey, the SA verifies compliance with 42 CFR 412.27(a), (b), and (c) by reviewing at least one patient record. If there are no patients in the unit at the time of the survey, the SA reviews patient records (at least one) for patients treated in the unit within 6 months of the date of the survey. If the psychiatric unit has not treated any patients during the 6 month period prior to the survey (i.e., there are no closed or active patient records available for review), the unit cannot demonstrate compliance with 42 CFR 412.27(a), (b), and (c), and the SA survey should be rescheduled to a later date when records will be available.

Hospitals/units that do not meet all exclusion criteria at the time of the SA onsite verification may still be eligible for exclusion. They must provide strong evidence documenting compliance with exclusion requirements at least 15 days prior to the beginning of the cost reporting period. If necessary, the SA contacts the hospital/unit again to confirm their compliance. However, a second onsite visit generally is not required to confirm evidence submitted subsequent to onsite verification. For example, if a rehabilitation hospital has a part-time director and is able to furnish proof that a full-time director will be employed prior to the start of the cost reporting period, no revisit is necessary.

## 3110. SA REVERIFICATION OF PPS-EXCLUDED HOSPITALS AND UNITS

A. Annual Reverification Process For Nonaccredited, PPS-Excluded, Rehabilitation Hospitals and Units:

o 120 days before the beginning of the next cost reporting period, the SA notifies the excluded hospital or unit (Exhibit 126) that it must self-attest to compliance with the appropriate requirements in 42 CFR s 412.23(b), 412.25, and/or 412.29.

o The SA includes a copy of the attestation statement (Exhibit 127) and the appropriate hospital or unit criteria worksheet (Form HCFA-437A or 437B Exhibit 73);

o The hospital/unit is to return the completed/signed worksheet and signed attestation statement to the SA office no later than 90 days before the beginning of its next cost reporting period;

o The SA transmits the completed attestation statement and worksheet, along with its recommendation for reverification, to the RO at least 60 days prior to the end of the hospital's cost reporting period for inclusion with other information necessary for determining exclusion from PPS.

B. Reverification Process For Rehabilitation Hospitals and/or Units Accredited by CARF Under CIRP or JCAHO.--Accredited rehabilitation hospitals or units may be presumed to meet the criteria in §§3104.B or 3106.C, excluding the 75 percent rule (verified by the intermediary and the director requirement (42 CFR 412.23(b)(5) or Part 412.29(f)(1), as appropriate). Accredited rehabilitation hospitals/units self-attest to compliance with the director requirement on Form HCFA-437A or Form HCFA-437B using the same procedure and processing timeframes as used for nonaccredited hospitals/units.

C. Reverification Process For Psychiatric Units of Hospitals:

o The SA uses the same process and timeframes as those used for nonaccredited rehabilitation hospitals and units to determine if the unit meets the specific criteria for psychiatric units in §3106; and

o The SA provides the psychiatric unit with the criteria worksheet for psychiatric units, Form HCFA-437 (Exhibit 73), along with Exhibit 126 and the attestation statement (Exhibit 127).

Hospitals/units that do not self-attest to meeting all exclusion criteria at the time of the annual self-attestation may still be eligible for exclusion. They must provide strong verifiable evidence documenting compliance with exclusion requirements at least 15 days prior to the beginning of the cost reporting period. If necessary, the SA contacts the hospital/unit again to confirm compliance. A SA on-site visit generally is not required to confirm evidence submitted subsequent to self-attestation.

## 3112. RO PROCEDURES FOR EXCLUSION FROM PPS FOR HOSPITALS AND UNITS

For initial exclusion from PPS, hospitals (except those now certified as psychiatric hospitals) and hospital units that meet the criteria of this section have been instructed in the Provider Reimbursement Manual to notify the RO of their eligibility for exclusion. Notification should be in writing and include the following: name of hospital, type of hospital/units, address, current provider identification number, name of contact person, FI, and a statement that the hospital/units(s) meets the criteria for exclusion. Notification should be made, where possible, no later than 5 months before the date the hospital becomes subject to PPS.

Hospitals and units that have already been excluded from PPS need not reapply for exclusion. These facilities will be reevaluated based on the criteria described in §3112.2 to determine if they still meet the PPS exclusion criteria.

If the RO does not receive notification of a hospital/unit meeting the criteria of this section but has knowledge that it should be excluded, the RO identifies the hospital/unit for exclusion.

Except for currently certified psychiatric hospitals, the RO notifies the hospital and the FI, in writing, 45 days prior to the start of the cost reporting period, of the excluded status of the hospital or unit(s) and of any new provider number(s). The RO coordinates these activities very closely with the servicing intermediary of the hospital. Prior to making a decision on hospital/unit exclusion, the RO determines whether the hospital/unit meets all exclusion criteria including those criteria that are the responsibility of the servicing intermediary.

PPS excluded or nonexcluded status for a hospital or hospital unit remains in effect for the entire cost reporting period for which the determination is made. If a change in meeting applicable criteria occurs during a cost reporting period or the hospital requests exclusion after the start of its cost reporting period, the status already determined for that period will remain for the duration of the period. However, any change in status resulting from the beginning or end of a hospital's participation in an approved demonstration project or State reimbursement control program will be effective on the date the change occurs, whether or not the date coincides with the start of a cost reporting period. A hospital may increase or decrease the space (square footage or number of beds) assigned to an excluded unit only at the start of the hospital's next cost reporting period.

### 3112.1 RO PROCEDURES FOR FIRST-TIME EXCLUSION OF HOSPITALS AND UNITS

When considering a hospital or hospital unit for exclusion for the first time, the RO has the SA and or the intermediary verify the facility's compliance with exclusion criteria, as follows:

- Psychiatric Hospitals.--The RO verifies through a review of records that the hospital currently participates in Medicare as a psychiatric hospital, and that the hospital's provider number identifies it as a psychiatric hospital. The hospital is not required to make a separate request for exclusion.

- Rehabilitation Hospitals.--The RO has the SA verify that the exclusion criteria in §3104 are met. As noted in §3108, a rehabilitation hospital may be presumed to meet certain criteria based on accreditation by the Commission on Accreditation of Rehabilitation Facilities (CARF) or by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). However, the SA should verify compliance with the medical direction requirement, and the intermediary should verify compliance with the 75 percent rule for hospitals other than new hospitals.

- Children's Hospitals.--The RO has the intermediary verify that the hospital has in effect an agreement to participate as a hospital and that a majority of the hospitals inpatients are individuals under the age of 18. The determination is to be based on the hospital's most recently filed cost report, unless there is an indication that the age of the patient population has changed

since the close of the period covered by the report. If the age of the patient population has changed since that period, the RO has the intermediary determine whether the age criterion is met by the patient population treated during the prior 6-month period. The intermediary may base the determination either on its knowledge of the provider or on a separate contact which results in an actual review of a sample of patient records.

o Long-term Care Hospitals.--The RO has the intermediary verify that the hospital has in effect an agreement to participate as a hospital and that the average length of inpatient stay is greater than 25 days. The average length of inpatient stay is to be computed by dividing the number of total inpatient days (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period. However, if a change in the hospital's average length of stay is indicated, the hospital's average length of stay is to be computed by the same method for the immediately preceding 6-month period. Rehabilitation hospitals meeting the length-of-stay criterion for exclusion as a long-term hospital are to be excluded as long-term hospitals, and should not be evaluated for exclusion under the rehabilitation hospital criteria. (See §3104).

There are additional requirements for long-term hospitals that occupy space in a building also used by another hospital (i.e., the host facility) or in one or more buildings located on the same campus as another hospital. The additional criteria for a "hospital-within-a-hospital" are:

- The hospital has a governing body that is separate from the governing body occupying space in the same building or campus, and is not under the control of the host facility or any third entity that controls both hospitals;

Note: For purposes of this section, "control" exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

- The hospital has a single chief medical officer who reports to the governing body and is responsible for all medical staff activities at the hospital, and is not employed by or under contract with either the host facility or any third entity that controls both hospitals;

- The hospital has a medical staff that is separate from the host facility, is directly accountable to the governing body of the hospital, and adopts and enforces medical staff bylaws including the criteria and procedures for granting medical privileges to individual practitioners;

- The hospital has a single chief medical officer through whom all adminiatrative authority flows, who exercises control and surveillance over all administrative activity at the hospital, and is not employed by or under contract with either the host facility or any third entity that controls both hospitals: and

- The hospital meets one of the following criteria:

+ The hospital performs the basic hospital functions specified in 42 CFR s 482.21 through 482.27, §482.30 and §482.42 through the use of employees or under contract or agreements with entities other than the host hospital or any third entity that controls both hospitals:

+ The cost of services obtained by the hospital under contracts or other agreements with the host facility or any third party that controls both hospitals do not exceed 15 percent of its total inpatient operating costs during the six-month qualifying period used to determine compliance with the length-of-stay criterion at 42 CFR 412.23(e)(2); or

+ For the initial six-month qualifying period the hospital has an inpatient population of whom at least 75 percent were referred to the hospital from a source other than the host hospital.

The SA will review documentation for hospitals that intend to operate as "hospitals-within-hospitals" in order to make an initial recommendation to the ROs regarding a hospital's compliance or noncompliance with the above criteria (See §3104D). Final determinations will be made on a case-by-case basis by the RO using whatever procedure it deems appropriate . In some instances, it may be necessary to authorize a SA on-site inspection of the hospital by the State agency to collect additional information.

o Psychiatric Distinct-Part Units.--The RO has the intermediary verify that the general criteria for exclusion for units in §3106 are met. The RO has the SA verify that the specific criteria for psychiatric units in §3106 are met.

o Rehabilitation Distinct-Part Units.--The RO has the intermediary verify that the general criteria for units in §3106 are met. The RO has the SA verify that the exclusion criteria in §3104 are met. As noted in §3108, a rehabilitation hospital may be presumed to meet certain criteria based on accreditation by CARF or by JCAHO. However, the SA should verify compliance with the medical direction requirement and the intermediary should verify compliance with the 75 percent rule for rehabilitation distinct-part hospital units other than new units.

o Cancer Hospitals.--The RO contacts the Office of Payment Policy, Bureau of Policy Development, to obtain a listing of the hospitals which have been designated as cancer hospitals.

## 3112.2. RO VERIFYING CONTINUED COMPLIANCE WITH EXCLUSION CRITERIA BY CURRENTLY EXCLUDED HOSPITALS OR UNITS

A. Self-Attestation Procedures For PPS-Excluded Hospitals and Units.--

1. Rehabilitation Hospitals/Units and Psychiatric Units.--Annual verification surveys for all previously-excluded rehabilitation hospitals and units, and psychiatric units are no longer required. The new procedures is as follows:

- At least 120 days prior to the beginning of the next cost reporting period, SAs provide (see Exhibit 126) excluded rehabilitation hospitals/units and psychiatric units with the attestation statement (Exhibit 127) and the appropriate Criteria Worksheet, Form HCFA-437, 437A, or 437B;

- Hospital/unit officials complete and sign the attestation statement and the appropriate Worksheet and return them to the SA no later than 90 days before the beginning of the next cost reporting period; and

- After receiving the hospital/unit's self-attestation materials from the SA, the RO notifies the hospital/unit (see Exhibit 193) that recertification has been approved.

o Previously excluded hospitals/units are required to report any change in operations (e.g., expansion or downsizing) to the appropriate HCFA RO and to provide the SA with a copy of the report within 10 days after the change occurs;

o The SA conducts annual validation compliance surveys at excluded hospitals/units;

o SAs continue to conduct complaint surveys at excluded hospitals/units;

o SAs continue to conduct first-time verification surveys in connection with a hospital/unit's first exclusion from PPS; and

o FIs continue to verify, on an annual basis, compliance with the 75 percent rule (see 42 CFR s 412.23 through 412.30) for rehabilitation hospitals and units.

B. RO Verifying Exclusion Eligibility of Other Facilities.--

1. Currently Certified Psychiatric Hospital.--A hospital currently participating in Medicare and identified by its provider number as a psychiatric hospital is excluded from PPS and is not required to make any special requests for exclusion.

2. Children's Hospital.--A hospital is an excluded children's hospital if it has in effect an agreement to participate as a hospital, and if the majority of its inpatients are individuals under the age of 18. The determination is based on the hospital's most recently filed cost report. If there is an indication that the age of the patient population has changed since the close of the period covered by the report, the RO uses data for the prior 6-month period, asking the servicing intermediary to verify whether the age criterion has been met (i.e., whether the majority of the hospital's inpatients are individuals under the age of 18). This may be based on the intermediary's knowledge of the provider, or based on a separate contact.

3. Long-Term Hospitals.--A hospital is an excluded long-term hospital if it has in effect an agreement to participate as a hospital and if the average inpatient length of stay is greater than 25 days. The RO bases its determination on the hospital's most recently filed cost report. If there is an indication that the length of stay has changed since the close of the period covered by the report, use data for the prior 6-month period, asking the servicing intermediary to verify whether the length of stay criterion has been met (i.e., whether the average length of stay is in excess of 25 days). Rehabilitation hospitals meeting the length of stay criterion as a long-term hospital are eligible for a long-term hospital exclusion from PPS and do not have to meet the special criteria established for these categories of facilities.

The "hospital-within-hospital" criteria described in §3112.1 apply to all long-term hospitals with cost reporting periods beginning on or after October 1, 1995. If the RO becomes aware of any long-term hospital operated in a building or campus occupied by another hospital, the hospital must be in compliance with the criteria described in §3112.1.

4. Cancer Hospitals.--The RO verifies through contact with the Center for Health Plans and Providers, that the hospital continues to be designated as a cancer hospital.

3112.3 Role of FIs In Reverification of PPS Excluded Hospitals and Units

The FIs are to verify the following:

- Rehabilitation Hospitals and Units.--75 percent rule applied to diagnoses.
- Children's Hospitals.--Age criterion.
- Long-Term Hospitals.--Length of stay criterion.
- All Distinct Part Units.--Unit is a separate cost center for cost finding and apportionment, meeting requirements of Provider Reimbursement Manual §2803.

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## 3200. ACTION BASED ON CHANGES IN PROVIDER ORGANIZATION, SERVICES, OR ACTION OF OTHER APPROVING AGENCIES

Notification that an entity has undergone organizational changes, added or relocated units, or received an accreditation may require a change in SA scheduling.

## 3202. CHANGE IN SIZE OR LOCATION OF PARTICIPATING SNF AND/OR NF

Under §1866 of the Social Security Act (the Act), the Secretary has the authority to enter into an agreement with an institution or an institutional complex to provide covered services to our beneficiaries. The provider agreement requires compliance with the requirements the Secretary deems necessary for participation in the Medicare or Medicaid program. See §1866(b)(2) and §1902 (a)(27) of the Act. On the effective date of the provider agreement, the institution or institutional complex is deemed to have met the requirements for participation based upon a survey of the institution or institutional complex as it was configured (i.e., bed size/bed location configuration) on the date(s) of the survey. HCFA's authority to regulate bed size changes in a SNF or a NF is based on the authority to ensure compliance with the provider agreement under §1866 of the Act and to further ensure that the configuration that has been approved for the institution or institutional complex does not so drastically change from that of the original certified configuration so as to endanger resident health and safety or otherwise change in a material fashion the identity of the entity that HCFA originally certified for program participation.

An institution or institutional complex may choose to participate in the Medicare and/or Medicaid programs either in its entirety (i.e., fully participating), or a portion thereof (i.e., a distinct part), but not both. If only a portion of an institution or institutional complex actually participates in either program it is classified as a distinct part and must meet the criteria found in §2762. For example, an institution has 4 wings that consist of 25 beds each. Three contiguous wings that contain 75 beds are dually participating (i.e., participating in Medicare and Medicaid). The fourth wing is only certified to participate in Medicare. It consists of 25 beds. Therefore, in this instance the institution is fully participating for purposes of Medicare (i.e., 100 beds) and a distinct part for purposes of Medicaid (i.e., 75 beds). The policies on bed size changes and changes in designated bed locations that are included in this section apply, regardless of whether an institution is fully participating (i.e., all beds within the institution or institutional complex are certified to participate in the Medicare and/or Medicaid program) or participating as or with a distinct part.

A SNF or NF may be:

- An entire institution for skilled nursing or rehabilitative care, such as a nursing home; or,
- A distinct part of an institution such as, a hospital, personal care home, assisted living facility, board and care home, domiciliary care facility, rest home, continuing care retirement community or nursing home.

An institution that is primarily for the care and treatment of mental diseases cannot be a SNF or NF.

A. Requirements for Distinct Part Certification.-- If the institution or institutional complex is participating as a distinct part SNF and/or NF, for a change to be approved the requested change in bed size must conform with the requirements to be classified as a distinct part. The term "distinct part" refers to a portion of an institution or institutional complex (e.g., a nursing home or a hospital) that is certified to provide SNF and/or NF services. A distinct part must be physically distinguishable from the larger institution and fiscally separate for cost reporting purposes. An institution or institutional complex can only be certified with one distinct part SNF and/or one

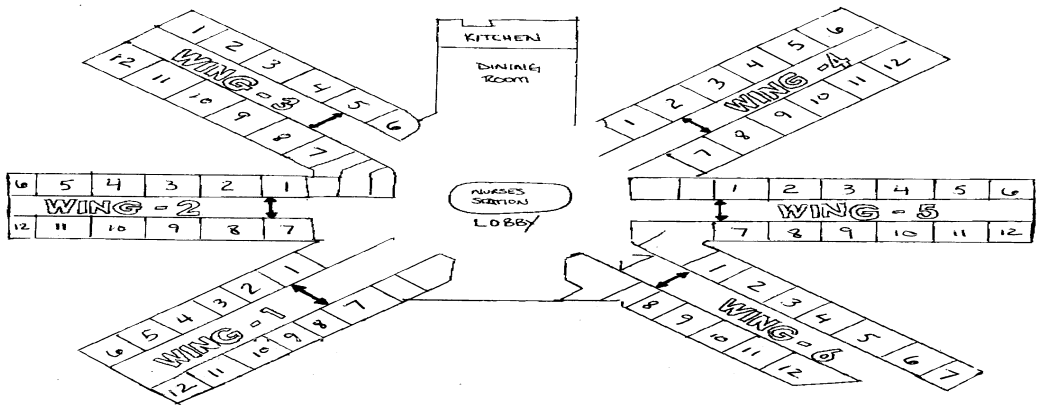


EXHIBIT I
FLOOR PLAN OF NURSING FACILITY

distinct part NF. A hospital based SNF is by definition a distinct part. Multiple certifications within the same institution or institutional complex are strictly prohibited. The distinct part must consist of all beds within the designated area. The distinct part can be a wing, separate building, a floor, a hallway, or one side of a corridor. The beds in the certified distinct part area must be physically separate from (that is, not commingled with) the beds of the institution or institutional complex in which it is located. However, the distinct part need not be confined to a single location within the institution or institutional complex's physical plant. It may, for example, consist of several floors or wards in a single building or floors or wards that are located throughout several different buildings within the institutional complex. In each case, however, all residents of the distinct part would have to be located in units which are physically separate from those units housing other patients of the institution or institutional complex. Where an institution or institutional complex owns and operates a distinct part SNF and/or NF, that distinct part SNF and/or NF is a single distinct part even if it is operated at various locations throughout the institution or institutional complex. The aggregate of the SNF and/or NF locations represents a single distinct part subprovider, not multiple subproviders, and must be assigned a single provider number. Exhibit I, above, is an illustration of a floor plan of a nursing facility followed below by examples which meet the requirements for a distinct part, as well as examples that do not meet the requirements for a distinct part. The purpose of the Exhibit is to assist the State and the RO in ensuring proper distinct part certification.

1. Meet Distinct Part Certification.--An institution or institutional complex can select any **one** of the following examples discussed in the context of Exhibit I above, that meets the requirements for distinct part certification.

o All rooms numbered 1 through 12 in wing 1 and all rooms numbered 1 through 12 in wing 2 constitute a distinct part. This option is approvable because it constitutes all beds in each wing.

o All rooms numbered 1 through 12 in wing 5. This option is approvable because it includes all beds in the wing.

o Room numbers 1 through 6 in wing 4 constitute a distinct part. This option is approvable because it includes all beds that constitute a single side of the corridor.

o Room numbers 7 through 12 in wing 2 and all rooms 1 through 12 in wing 1 constitute a distinct part. This option is approvable because it includes all beds in wing 1 and all beds that constitute a single side of the corridor in wing 2.

2. Do Not Meet Distinct Part Certification.--Neither of the examples discussed below, in the context of Exhibit I above, meet the requirements for distinct part certification.

o Room numbers 1 through 12 in wing 1 and rooms 3,4, and 5 in wing 6 do not constitute a distinct part. This option is not approvable because of the inclusion of the three rooms in wing six.

o Room number 2 in wing 1, room numbers 5 and 7 in wing 6, and room numbers 4,5,6, 10, 11, and 12 in wing 4. This option is not approvable because the distinct part area must be physically separate from (that is, not commingled with) the beds of the institution or institutional complex in which it is located.

B. Changes in Bed Size of Participating SNF and/or NF.--When an institution or institutional complex not previously certified as or with a SNF and/or NF establishes a SNF and/or NF, it must be initially certified and periodically recertified. If an institution or institutional complex has an existing SNF and/or NF agreement, it may elect to change the number of beds that are certified to participate in the Medicare or Medicaid program up to two times per cost reporting year in accordance with the requirements set out below. Where a change in the size of an SNF also impacts the size of a NF, or vice versa, this represents one change for the SNF and one change for the NF. An institution or institutional complex that is participating in the Medicare program can find these same requirements in §2337 of the Provider Reimbursement Manual, Part I. An institution or institutional complex may only change the bed size of its SNF and/or its NF once on the first day of the beginning of its cost reporting year and again on the first day of a single cost reporting quarter within that same cost reporting year in order to effect one of the following combinations:

o An increase in its bed size on the first day of the beginning of its cost reporting year and an increase in its bed size on the on the first day of a single cost reporting quarter that falls within the same cost reporting year, or;

o An increase in its bed size on the first day of the beginning of its cost reporting year and a decrease in its bed size on the first day of a single cost reporting quarter that falls within the same cost reporting year, or;

o A decrease in its bed size on the first day of the beginning of its cost reporting year and an increase in its bed size on the first day of a single cost reporting quarter that falls within the same cost reporting year.

At no time can the RO or the SA approve two decreases in the bed size of an institution within the same cost reporting year.

The institution or institutional complex may submit only ONE change in bed size at a time. Furthermore, an institution cannot request a change in its bed size just because it undergoes a change

of ownership (CHOW) or because it has been approved to change its cost reporting year. In either of these circumstances, it is still bound by the filing requirements found in subsection C.

A request for a change in the number of certified beds cannot be approved on a retroactive basis. All changes are made on a prospective basis only in accordance with the effective date indicated above. The institution requesting a change in bed size must submit a written request to the RO or SA (as appropriate) in conformance with the requirements found in subsection C. An institution or institutional complex can not self-designate the effective date of a change in bed size.

C. General Request Filing Requirements.--An institution or institutional complex seeking a change in the number of Medicare and/or Medicaid certified beds must:

o Submit a written request to the RO or SA (as appropriate) for the change 45 days before

- the first day of its cost reporting year to effect a change on the first day of its cost reporting year or;

- the first day of a single cost reporting quarter within the same cost reporting year at which time it seeks to change its bed size to effect a change on the first day of the designated cost reporting quarter.

o Submit floor plans identifying all areas of the institution or institutional complex with the current certified bed configuration and the proposed certified bed configuration in order for the RO or SA to determine that the proposed change is in fact, in conformance with the rules for full participation or distinct part certification, whichever applies.

o Include a reference to the cost reporting year of the institution or institutional complex. If there has been a change in the cost reporting year originally selected by the institution or institutional complex at the time of its initial certification, submit a copy of the letter submitted to the fiscal intermediary and the fiscal intermediary's response to the request.

D. Exceptions-- There are certain situations (described below) which we believe warrant an exception to the above policy. Therefore, even if the institution or institutional complex has been approved for a change in bed size in accordance with the policies articulated above, the institution or institutional complex may be granted a change in bed size on the basis of one of these situations. To request a change in bed size based on one of these situations, the institution or institutional complex must file a written request with the RO or SA (as appropriate) 45 days before the first day of its next cost reporting quarter, at which time the request will be effective if approved, along with floor plans identifying all areas of the institution or institutional complex with the current certified bed configuration and the proposed certified bed configuration. An exception may be granted based only on one of the following situations:

1. Life Safety Code (LSC) Requirements.--An exception may be granted if the request is to reduce the size of the SNF or NF to avoid being out of compliance with LSC requirements (e.g., sprinkler installation). The proposed bed configuration must be separated from the rest of the institution or institutional complex by a 2-hour fire wall, so that there is no danger of the fire spreading there from other parts not meeting safety requirements. In this case, the proposed reduction in the size of the SNF or NF may be established with an effective date that is requested by the institution or institutional complex, but not earlier than the date that the separation can be documented. A full survey by the fire authority must be performed if the reason for the request is to limit noncompliance with LSC requirements.

2. Elimination of Distinct Part.--An exception may be granted if an institution or institutional complex concludes that it wants to become fully participating (i.e., all beds within the institution or institutional complex are certified to participate in the Medicare and/or Medicaid program). If the institution or institutional complex decides to become fully certified to participate in the Medicare and/or Medicaid program, **it cannot return** to distinct part certification until, at the earliest, the beginning of its next cost reporting year.

3. Enlargement Through Construction, Purchase or Lease of Additional Space. An exception may be granted if the institution or institutional complex requests to increase the size of its SNF or NF to include space acquired through new construction, purchase or lease (e.g., constructing a new wing, purchasing an adjacent building or leasing a floor in a hospital).

E. Change in Designated Bed Location(s).--An institution or institutional complex may request to change its designated bed locations, as long as there is no change in the number of beds certified to participate in the Medicare and/or Medicaid program, by submitting a written request to the SA or the RO 30 days in advance of such a change. In addition, the institution or institutional complex must submit floor plans identifying all areas of the institution or institutional complex with the current certified bed configuration and the proposed certified bed configuration in order for the RO or SA to determine that the proposed change is in fact, in conformance with the rules for full certification or distinct part certification, whichever applies. The institution or institutional complex must adhere to the notification requirements found in 42 CFR 483.10(b)(11)(ii)(A) and the residents rights requirements found in 42 CFR 483.10(o). The request must be approved by the RO or SA before the institution or institutional complex makes the change. No changes are made on a retroactive basis.

F. RO or SA (as appropriate) Actions Upon Receipt of Written Request for Change in Bed Size/Location.--The RO or the SA must take the following actions when reviewing a request for a change in bed size:

o Date stamp the letter from the institution requesting a change in bed size with the date it was received by the RO or SA;

o Verify the cost reporting year selected by the institution or institutional complex using the OSCAR system. The cost reporting year of the provider must match what is contained in OSCAR. If the reported cost reporting year is different than that found in OSCAR it would be as a consequence of a change in cost reporting year (for Medicare) which must be approved by the fiscal intermediary in accordance with the requirements found in 42 C.F.R. 413.34(f). Absent such a change, the institution or institutional complex must adhere to the cost reporting year selected at its initial certification;

o Document information as required under §2764;

o Complete the Form HCFA-1539 reflecting the change in bed size/designated bed location(s) if the request is approved;

o Notify the institution or institutional complex in writing of the RO or SA decision to either approve or disapprove the request prior to the effective date of the change. If approved the letter must include the effective date of the change in bed size and/or designated bed locations, the total number of beds certified and the designated bed locations. If disapproved the letter must explain the requirement(s) not met;

o Send a copy of the letter notifying the institution or institutional complex of the RO or SA decision to approve or disapprove the request to the appropriate fiscal intermediary;

o Update the OSCAR system.

Usually, advancing the scheduled SA standard survey to recertify the changed configuration is unnecessary. A telephone contact often resolves most questions, such as changing bylaws, staffing, or other issues regarding the capacity of the institution or institutional complex to furnish the level of care contemplated in the long term care requirements. The SA must advance the survey schedule and perform a survey if;

o There is reason to question whether the institution remains in compliance with the long term care requirements (e.g., the proposed relocation site is unsuitable);

o Information suggests that as a part of the change, a different governing body or managing personnel directs the distinct part. (See §3210.); or

o The area within the physical plant to be certified has not been subjected to a life safety code survey.

G. Evaluation.--The SA bases its evaluation of the proposed certified area upon the following guidelines.

1. Shared Facilities and Services.--Rarely is a distinct part SNF or NF so completely self-contained that it independently meets all of the long term care requirements. Therefore, to the extent necessary, the SA evaluates services, facilities, and activities located outside the distinct part that are used by the distinct part's residents. This evaluation is not an assessment of whether the distinct part meets the requirements to be considered provider-based for purposes of Medicare reimbursement.

Often, the distinct part will share central supporting services such as dietary, housekeeping, and plant maintenance with the rest of the institution or institutional complex. Depending on the size and type of the institution or institutional complex, the distinct part may also have shared administration and supervisory, medical, and therapeutic services.

The primary consideration in the evaluation of shared services is whether the sharing can be done without sacrificing the quality of care rendered to distinct part residents or endangering their health and safety. The distinct part must demonstrate a capacity to provide all of the services, facilities, and supervision required by the long term care requirements. For this reason, the SA may need to consider the total staff of an institution or institutional complex, particularly with respect to the amount of shared responsibilities.

2. Effect of Hospital Accreditation or Certification on SNF or NF.--Make no assumption regarding a distinct part SNF or NF's compliance with long term care requirements on the basis of the institutional or institutional complex's accreditation by the Joint Commission on Accreditation of Healthcare Organizations or AOA or the institution or institutional complex's Medicare participation. Survey and evaluate the institution or institutional complex to determine its compliance with all of the long term care requirements.

3. SNF or NF as Distinct Part of a Psychiatric Hospital.--The guidelines for the identification of a distinct part SNF or NF, regardless of the type of institution or institutional complex in which it is located, are generally applicable. However, there are special factors to consider when an institutional complex is certified to participate as a psychiatric hospital.

A SNF or NF cannot be certified if it is primarily for the care and treatment of mental diseases. In the context of a psychiatric hospital, for example, the presumption is that in most cases a SNF or NF distinct part of such a hospital is designed primarily for the care and treatment of patients with mental diseases. A distinct part SNF or NF cannot be established unless the psychiatric hospital either has a separate medical-surgical unit which is participating as a distinct part general hospital

or has an arrangement with a community hospital for transfer to the hospital and back to the distinct part for post-hospital convalescence when a beneficiary requires medical-surgical services. In determining whether a distinct part SNF or NF is primarily for the care and treatment of mental diseases, the SA must look at the primary purposes for the unit's existence, in combination with the requirements discussed above. A psychiatric hospital can have such a unit or section certified as a distinct part SNF or NF, only if the primary purpose of the unit is to provide medical services and the hospital meets one of the requirements discussed in the last sentence of the preceding paragraph.

In addition, a distinct part SNF or NF of a psychiatric hospital would also have to be licensed pursuant to the State or local law which provides for licensing of institutions of a type which qualify as SNFs, i.e., the distinct part would have to be licensed as a nursing home.

H. Survey Considerations.--Although an immediate survey is not mandatory, the SA must complete Form HCFA-1539 promptly to report the change in size and location of the SNF or NF. Furthermore, the SA completes a spell of illness certification for any components of the institution or institutional complex that are being removed from inclusion in the SNF or NF. (See §2164.) If, in order to process this certification, the SA finds that survey is necessary, it may perform a full standard survey.

## 3206. EXISTING ESRD FACILITY RELOCATION, EXPANSION, OR ADDITION OF NEW SERVICE

A new application is required when an ESRD facility relocates, expands, or adds a new service. An ESRD facility may relocate in order to expand because public transportation will make it more accessible to its patient population or because it wishes to add new services (see §2274).

## 3210. CHOW OF PROVIDERS AND SUPPLIERS

Regulations covering CHOWs are in 42 CFR 489.18.

The initial development of facts concerning a CHOW is made by the SA. After the SA concludes its fact-finding, it forwards the findings, with supporting documentation, to the RO with its recommendations for determination.

When a provider undergoes a CHOW, the provider agreement is automatically assigned to the new owner unless the new owner rejects assignment of the provider agreement. If the new owner rejects this assignment, the provider organization will not be able to participate in the Medicare program without going through the same process as any new provider, i.e., applying for participation, undergoing Office of Civil Rights (OCR) clearance and an initial survey, having an effective date of participation assigned based upon regulation, etc. Automatic assignment of the existing provider agreement to the new owner means the new owner is subject to all the terms and conditions under which the existing agreement was issued. Terms and conditions include, but are not limited to:

A. Existing PoC.--The new owner must meet the time frames for correcting deficiencies cited in the existing PoC. A CHOW is not a basis for extending the time given for correction. Documented evidence of effort and progress and the absence of jeopardy to patient health and safety remain the only acceptable reasons for giving additional time for correction of deficiencies.

B. Compliance With Health and Safety Standards.--Assignment of an existing provider agreement assumes that a CHOW will have no adverse effect on patient health and safety. Consequently, a survey may not be required. If, however, there is any indication that patient care has deteriorated following a CHOW, the State must conduct a survey. If such a survey indicates noncompliance, the RO applies the enforcement action that is applicable to the provider/supplier type and appropriate to the level of noncompliance.

C. Compliance With Ownership and Financial Interest Disclosure Requirement.--Disclosure of ownership information is not a prerequisite to assignment of the agreement. However, ownership disclosure is a statutory requirement for all participating providers and suppliers. Upon learning of an ownership change, the SA will forward Form HCFA-1513 to the new owner for completion. Refusal to submit the requested information is a basis for termination. In no instance may the new owner be certified and issued a new provider agreement until a completed Form HCFA-1513 is received. The new owner must complete and return the form within 30 days of receipt.

D. Compliance With Civil Rights Requirements.--The RO notifies the OCR-RO of CHOWs of providers. Assignment of the existing provider agreement is not withheld pending civil rights clearance, and a new agreement can be issued before clearance by the OCR-RO is obtained. However, under these circumstances, a restricted provider agreement is issued with a contingency clause which states that if OCR clearance is not obtained, any payments made during the period will be recouped from the facility as of the effective date of the CHOW.

E. All Medicare Sanctions and Penalties.--Medicare sanctions and penalties are assigned to the new owner with the following exceptions:

1. NATCEP.--The restrictions preclude a State from approving (and requiring a State to withdraw from) Nurse Aide Training and Competency Evaluation Programs (NATCEPs/CEPs) offered by or in facilities that, within the previous 2 years, have been found to be out of compliance with certain CoPs. If there is a CHOW before such a 2-year restriction has run its course, whatever remains of the 2-year period will not be transferred to the new owner.

2. Money Owed in Fraud Cases.--The new owner is not responsible for money owed the Federal Government due to a determination that the previous owner is personnally guilty of fraud. (However, if a determination of fraud is made against the corporation, and if the corporation is purchased and not incorporated as a new and separate corporation by the new owner, the new owner is subject to all Medicare penalties, sanctions, and liabilities.

## 3210.1 DETERMINING OWNERSHIP

A. General.--For certification and provider agreement purposes, the provider is the party directly or ultimately responsible for operating the business enterprise. This party is legally responsible for decisions and liabilities in a business management sense. The same party also bears the final responsibility for operational decisions made in the capacity of a "governing body" and for the consequences of those decisions.

Whether the owning party owns the provider enterprise premises or rents or leases them from a landlord or lessor is immaterial. Of course, if the owner enters into an agreement which allows the "landlord" to make or participate in decisions about the ongoing operation of the enterprise, this indicates that the owner has entered into either a partnership agreement or a management agency agreement instead of a property lease. A new partnership agreement constitutes a CHOW.

To determine ownership of any provider enterprise or organization, the SA determines which party (whether an individual or legal entity such as a partnership or corporation) has immediate authority for making final decisions regarding the operation of the enterprise and bears the legal responsibility for the consequences of the enterprise's operations.

CHOW processing is necessary for program participants that have Health Benefit Agreements or Provider Agreements in the Medicare program (hospital, RPCH, SNF, HHA, hospice, CORF, OPT/SP providers and, CMHC) because it must be determined who the responsible party is under the agreement. For the same reason, CHOW processing is necessary for supplier participants that have category-specific agreements with the Secretary (RHC, ASC, and FQHCs) or that must file cost reports (e.g., ESRD facilities). Somewhat less extensive CHOW processing is necessary for the remaining supplier types without agreements or cost report requirements (PTIP, OTIP, and PXR) to ensure compliance with the statutory requirement for ownership disclosure and to ensure that the program has current, accurate records regarding participants.

B. SA Actions To Be Taken Following CHOW.--

1. All Cases.--The SA mails a set of initial certification forms to the new owner as soon as possible. (See Exhibit 63.) The SA sends Form HCFA-1561 to the new owner for signature with a footnote. The footnote lists the original provider number, the name of the previous owner (the owner of record before the change of ownership), and his or her address, and it is placed in the empty space provided after the blocks furnished for the successor's signature, title, and date. This serves to convey to each new owner at the outset that he or she is being assigned the previous owner's provider agreement (in the words of Form HCFA-1561) "subject to all the conditions specified in [the] agreement and 42 CFR Part 489, to include existing plans of correction...." This is important, because some providers have professed ignorance that they have been assigned the previous owners' provider agreements, subject to the same terms and conditions that applied to the

previous owners. This was the central point in the U.S. v. Vernon Home Health, Inc. case. It must be made clear to the new owners or prospective new owners what their rights and responsibilities are under the applicable Federal statutes and regulations, and it must be done as early in the process as possible to enable these individuals to make informed decisions. Whenever an owner is contemplating or negotiating the sale of a provider, he or she notifies the SA or the RO, as required at 42 CFR 489.18(b). The SA or the RO asks the prospective new owner if he or she intends to participate in the Medicare program, and, if so, whether he or she intends to do so by accepting assignment of the previous owner's provider agreement or by applying for a new provider agreement. This will prevent the confusion we have seen in the past and reduce litigation.

Sometimes the RO is unaware that a change of ownership has taken place until after the fact; sometimes until months after the sales agreement has been consummated. In these cases, there is nothing that can be done except to ensure that the new owner understands the consequences of becoming a Medicare provider and accepting assignment of the previous owner's provider agreement. Regardless of when the new owner is advised of the automatic assignment of the previous owner's provider agreement (if the provider/supplier explicitly refuses to accept assignment, notify the RO immediately because payments may have already been made under the old provider agreement), The SA uses the footnote and has the new owner sign under the set of blocks on Form HCFA-1561 labelled "Accepted for the Successor Provider of Services by." This is an important step because it documents the fact that the new owner realizes that there is an assignment of the agreement. The SA informs the new owner of the requirement to submit the documents to its office no later than 2 working days after the consummation of the CHOW transaction, or, if the transaction occurred more than 2 days ago, as soon as possible. The SA may accept most of the documents prior to the consummation of the CHOW transaction. However, because some CHOW transactions never are consummated, these documents should not be forwarded until the transaction has been completed. Similarly, the SA can only complete its processing after the CHOW date.

If the new owner indicates a desire not to participate in the program, the SA alerts the RO immediately by telephone and, if Medicaid is involved, the SMA. The SA obtains a written notice regarding the owner's desire not to participate, and forward it to the RO or to the SMA.

A CHOW, per se, does not require a special survey. However, if there is any reason to believe that the quality of services have deteriorated following the CHOW, or that new locations are being added or that different types of services will be provided, the SA may wish to conduct a survey.

For physical therapist in independent practice (PTIP) and occupational therapist in independent practice (OTIP) suppliers, the SA obtains an Ownership and Control Interest Disclosure Statement (Form HCFA-1513), the applicable Request to Establish Eligibility form, and a statement from the new owner informing the SA of the circumstances of the CHOW. In the case of these suppliers, a specific individual is approved to participate, not an organization or enterprise, as is the case with all other providers and suppliers. Consequently, there can be no CHOW in the usual sense. When a certified PTIP or OTIP ceases to participate, his or her office(s) and employees no longer participate. The SA notifies the RO that the supplier has ceased to participate. If a new owner of the former supplier's office wishes to participate as a PTIP or OTIP, he or she must apply, undergo a survey, and be approved by the RO.

For portable X-ray suppliers, the SA obtains a Form HCFA-1513, the applicable Request to Establish Eligibility form, and a statement from the new owner informing it of the CHOW effective date. Because there is no agreement to transfer in these cases and no cost report to be filed by the outgoing owner, it is not critical that the SA establish the CHOW date with the certainty required for providers and suppliers with Medicare agreements and/or cost reporting requirements.

For all providers, and suppliers with category-specific agreements (for example, RHC and ASC), and ESRD facilities, the SA obtains a Form HCFA-1513, the applicable Request to Establish Eligibility form, an Expression of Fiscal Intermediary Preference, and documentation that proves a CHOW took place as well as exactly when it took place. The SA has all facilities complete an Expression of Fiscal Intermediary Preference form in every case to alert it to the instances in which the new owner is part of a HCFA-recognized chain organization that uses a FI not commonly used in its State. Multi-regional chain operations due to their compelexity are to be referred to the RO for adjudication in accordance with 3210.3 The SA The SA includes on the Fiscal Intermediary Preference form a blank to be completed by the new owner indicating the ending date of the fiscal year that the new owner intends to use.

For providers and suppliers with category-specific agreements, the SA obtains two signed originals of the applicable Medicare agreement form.

For providers, the SA obtains the applicable form required by OCR (HHS-441) and the appropriate attachments. See Exhibit 63 for a full listing of documents for the SA to submit to the RO.

2. CHOW During Termination Development.--The SA apprises the provider/supplier that termination actions already in process will not be postponed and the termination will only be avoided if compliance is attained. The SA notifies the RO by telephone of the CHOW and proceed to obtain and process the usual CHOW documents.

3. CHOW During "Reasonable Assurance Period".--Following termination, a new owner may request approval for reentry, subject to operation of the facility for a certain period of time without recurrence of the deficiencies which were the basis for termination. The reentry may be through the SA survey process or through an accrediting organization recognized by HCFA. The RO makes the determination as to whether the institution is eligible for readmission based on demonstrated compliance over a specified period of time. This "reasonable assurance period" will not be altered because a new owner takes over the provider organization or because the provider organization becomes accredited. If the new owner wishes to proceed with reentry, the SA notifies the RO by telephone and obtains and processes the usual CHOW documents (see §2016).

4. Transfer Agreement Required of New Owner.--For SNFs and NFs, a new owner will have to negotiate and submit a hospital transfer agreement relating to the new owning entity.

C. Certification of Accredited Providers/Suppliers Which Change Ownership.--While JCAHO and AOA accreditation are not transferable to a new entity, accreditation does not automatically lapse when ownership changes. In the case of JCAHO or AOA accreditation, an accredited hospital must notify JCAHO or AOA within 30 days of the CHOW. Accreditation is continued until JCAHO or AOA has determined whether a resurvey is necessary.

If an accredited hospital is involved in a CHOW, the SA does not survey the facility. The SA secures the usual CHOW documents and forwards them to the RO.

If a participating JCAHO hospital merges with a nonaccredited participating or nonparticipating hospital, JCAHO will almost always provisionally extend its accreditation to the nonaccredited facility as if it were deemed accredited. In these cases, however, the SA does not treat the nonaccredited facility as if it were deemed accredited. Pending an accreditation survey and decision, the SA considers it a nonaccredited facility.

These same principles are applicable to other accredited facilities.

D. CHOW Situations.--

1. Sole Proprietorship.--If a provider of services is an entity owned by a single individual, a transfer of title to the enterprise to another person or firm, whether or not including transfer of title to the real estate, constitutes a CHOW. It is also a CHOW if the former owner becomes one of the members of a partnership or corporation succeeding him as the new owner.

2. Partnership.--In a partnership, the removal, addition, or substitution of an individual as a partner in the entity, in the absence of an express statement to the contrary (as permitted by State law) dissolves the old partnership and creates a new partnership and is a CHOW. State laws may vary regarding exceptions to this rule. If a question is raised by the surviving partners, the SA submits the facts without delay to the RO for a decision (or to the appropriate State authorities in a Medicaid-only case).

3. Corporation.--In an incorporated provider entity, the corporation is the owner. The governing body of the corporation is the group having direct legal responsibility under State law for operation of the corporation's entity, whether that body is a board of trustees, a board of directors, the entire membership of the corporation, or is known by some other name. Even though one or more members of this governing body changes, and regardless of whether ownership of the corporation stock is transferred, there would not be a CHOW as long as the same corporation continues to be the legal entity responsible for operation of the provider organization.

A merger of one or more corporations with the Medicare-participating provider corporation surviving (i.e., a merger "into" the participating corporation) is not recognized as a CHOW of the surviving corporation. Also:

- If the corporation that survives is not the former owner of the provider entity, there is a CHOW; and

- Consolidation or merger of two or more corporations that results in the creation of a new corporate entity having ownership control over a provider organization constitutes a CHOW. The SA may need to refer to a corporation's bylaws (on record with the State government) or board meeting minutes as it researches difficult cases.

4. Leasing.--When the entire participating provider facility is leased, the provider agreement with the former operator of the facility is assigned and constitutes a CHOW. If only part of the provider is leased, the original provider agreement remains in effect only with respect to the unleased portion. The lease of part of the facility constitutes a change of ownership. The SA does a survey and prepares a certification covering the leased portion as a new provider.

When a new lease arrangement goes into effect at a participating facility, the SA obtains documents that indicate which individual or entity has first level authority over, and responsibility for, the provider located within the leased premises.

5. Management Firm Operating Institution For Owners.--A firm which contracts with the owners to manage an enterprise, subject to the owners' general approval of operating decisions, is an agent of the owners rather than a partner or successor. If management in that sense is turned over to a management firm, this would not constitute a CHOW even though the management firm may appear to have wide latitude in making decisions, and even though its fee may be based on the net revenue or profit the facility receives from furnishing services.

The only case in which operation under a management agreement would constitute a CHOW is when the owner has relinquished all authority and responsibility for the provider organization. In questionable cases, the SA obtains and submits the management agreement to the RO along with its analysis and recommendation.

If a provider enterprise has been placed in the hands of a management firm and there is cause to suspect a problem in regard to patient care, the SA schedules and performs a survey.

E. CHOW Analysis General Rules.-

o A State licensing decision based upon a CHOW analysis conducted under the State's criteria is not necessarily relevant to a Medicare CHOW determination. The Medicare determination must be made based exclusively on Medicare regulations and policies;

o There can be no CHOW, i.e., transfer of Medicare participation, assignment of the provider agreement, and provider number, if there is no functioning provider enterprise in existence. If a provider ceases operations, it no longer meets the definition of any provider type and no longer has a right to a provider agreement or identification number;

o As a rule, when a provider organization is sold, the Medicare provider number stays with it. A buyer is assigned the provider number and the provider agreement if the buyer purchases a participating provider organization. A provider number cannot be sold. A provider identification number is not the "property" of any individual or legal entity. The number is issued by the Medicare program and is under the control of the Secretary of DHHS, subject to law, regulation, and program policy;

o To understand whether a CHOW took place in complex situations such as corporate reorganizations, it is often helpful to construct a simple "before and after" ownership diagram of the legal relationships among the owning entities and providers involved. The two-part diagram visually displays the ownership relationships as they appeared before and after the date of a possible CHOW;

o In general, a CHOW recognized by the Medicare program is considered to have taken place at 12:01 a.m. on the date specified (i.e., in the first minute of the 24-hour day). Legal responsibility and the right to payment changes over when the clock moves past midnight into the CHOW effective date;

o In general, the key date regarding a newly-formed corporation is not the incorporation date (the date the corporation came into legal existence), but the date a provider was conveyed to the new corporation. Sometimes a new corporation becomes legally responsible for a provider the moment the corporation comes into existence, but there must be documented evidence that this is the case. It cannot be assumed;

o It is not possible to know beforehand whether a CHOW will take place on a planned CHOW date. In every case, one must wait until after a proposed CHOW date to determine whether the planned CHOW event actually occurred. This means it is impossible to process a CHOW prior to the effective date; and

o The mere sale of any number of shares of an owning corporation does not constitute a Medicare CHOW because the responsible legal entity, the corporation, remains in place. For corporations that do not issue stock but are controlled by a "member" or "members" (which can be individuals, partnerships, or other corporations), the same principle holds true: a change in the individuals or entities controlling or owning the corporation is not relevant for CHOW purposes.

## 3210.2. RO ROLE IN CHOW DETERMINATION

The RO reviews the SA's recommendation and, if it concurs that a CHOW has taken place, it annotates the certification file to reflect the change and:

o For providers and suppliers that require approval, the RO issues a notice letter to the facility that recognizes the CHOW date. The RO sends copies of the letter to the SA, the SMA, the OCR-RO, and the FI(s). It is not necessary to achknowledge CHOWs that have taken place at the remaining supplier types;

o For providers and suppliers that require approval, the RO signs the two original agreement forms previously signed by an authorized representative of the new owning entity and forwarded to the RO by the SA. The RO retains one original agreement form in its certification file and encloses the other with the notice letter to the facility;

o For providers and ESRD facilities, the RO prepares a Provider Tie-In Notice (Form HCFA-2007) and forward it to the FI. If there is a change in FI, the RO sends copies of Form HCFA-2007 to the old and the new intermediaries. (See §3210.4);

o For all CHOWs, the RO should ensure that a kit of certification documents reflecting the change and all available current information is entered in the OSCAR system.

As corporate structures have become increasingly complex, it has become more difficult for professionals in nonlegal entities to discern all of the management and control relationships in individual situations and to determine accurately whether or not a CHOW has occurred for purposes of the Medicare program. The RO should refer all CHOW determinations which are in any way complicated by the intricacies of the case or otherwise require professional legal expertise to the appropriate Regional Attorney.

## 3210.3 CHOWS INVOLVING MULTI-REGIONAL CHAIN ORGANIZATIONS

When a CHOW involves a multi-regional chain organization, a lead or coordinating RO is designated. For certification purposes, this will typically be the RO serving the State in which the headquarters of the chain is located. See §4501 ("Change of Ownership Procedures") in the Intermediary Manual. The coordinating RO will notify all affected ROs of its lead role, make a CHOW determination that is uniform for all regions, and notify all affected ROs of the determination.

Exceptions to the lead RO procedure can occur. In an example involving 100 commonly-owned hospitals in 8 regions, not all of the transactions met the definition of a CHOW under the regulations. Many of the transactions required individual, detailed analysis. In this case, no coordinating RO was designated because no uniform circumstances existed. In any situation in which the RO believes a coordinating RO may need to be designated, contact CO for guidance.

## 3210.4. OTHER CHANGES RELATED TO CHOW -- RO PROCEDURES

The new owner of a provider has the opportunity to nominate a different intermediary and to change the provider's fiscal reporting period. (See §4501.1 of the Intermediary Manual.) There are also some instances in which the RO must assign a different provider number.

A. New Owner Requests Different Intermediary.--All participating providers which change ownership will be asked by the SA to complete an Expression of Fiscal Intermediary Preference form. The current intermediary is normally expected to continue and, if a change is not requested, is designated on the letter of acceptance sent to the provider.

However, should the new owner request a different intermediary, the RO determines whether or not the request can be honored before sending the CHOW acknowledgment letter. A typical reason for changing to a different intermediary is that the provider has come under the ownership of a HCFA-recognized chain organization which has a HCFA-designated single intermediary that differs from the intermediary normally designated for providers in the State. When the HCFA determines that the designation of any intermediary other than that requested by the new owner would result in more effective and efficient administration of the program, the request will not be granted. For doubtful cases, DHSQ consults with the RO Division of Medicare as to an approvable intermediary.

B. New Owner Sets Different Fiscal Reporting Period.--At the time of a CHOW, the new owner can select its fiscal reporting period. However, the new owner must file its initial cost report covering a period of at least 1 month of provider operations under the program, but no more than 13 months of provider operations under the program.

The SA reports to the RO what fiscal period the new owner plans to use. If the RO does not have documentation from the new owner as to the period it has chosen, it should confirm the period with the new owner. The RO indicates the selected fiscal year ending date on Form HCFA-2007. All subsequent requests for changes in the fiscal reporting period are processed by the intermediary.

C. New Provider Number Must Be Issued.--In most cases, the identification number previously assigned to the provider organization stays with the provider organization, regardless of which legal entity is the owner. A new number is not assigned based on a CHOW. There are exceptions, however. These exceptions involve cases in which the form of the provider number indicates a particular status of the provider or supplier to which it is assigned, and that status has changed as a result of the CHOW. The RO should note in the CHOW notice letter that one identification number is being retired effective with the CHOW date and a new one is being issued. The RO also includes this notice on Form HCFA-2007.

Before issuing a CHOW acknowledgement letter, the RO should review §2779, Assignment of Provider and Supplier Identification Numbers, to be sure the previously-assigned identification number continues to be appropriate. For additional instructions regarding provider identification numbers in merger and CHOW situations, see §2779.F. Following are the most likely examples of the need to issue a new identification number as a result of a CHOW:

A. ESRD.--An ESRD facility can be classified as a hospital-based located on the hospitals' premises (having an identification number in the series 00-2300 through 00-2499), as a hospital satellite off the hospitals' premises (having an identification number in the series 00-3500 through 00-3699), or as non-hospital/freestanding (having an identification number in the series 00-2500 through 00-2899). If its classification changes as a result of a CHOW, the RO retires its original number and issues a new number in the appropriate form, effective with the CHOW date. If its location changes as a result of a CHOW, the RO has the SA conduct a survey of the new location.

B. RHC.--A RHC can be classified as freestanding (having an identification number in the series 00-3800 through 00-3974 or 8900-8999), or as provider-based (having an identification number in the series 00-3975 through 00-3999, 00-3400 through 00-3499, or 00-8500 through 00-8899). If its classification changes as a result of a CHOW, the RO retires its original number and issue a new number in the appropriate form, effective with the CHOW date.

## 3210.5. NEW OWNER REFUSES TO ACCEPT ASSIGNMENT OF THE PROVIDER AGREEMENT

A. New Owner Refuses To Accept Assignment of Previous Owner's Provider Agreement.--A new owner may refuse to accept assignment of the previous owner's provider agreement, but this means the provider agreement terminated effective with the CHOW date. The refusal to accept assignment should be put in writing by the new owner and forwarded to the RO 45 days prior to the CHOW date to allow for the orderly transfer of any beneficiaries that may be patients of the provider. The refusal can take the form of a letter from the prospective owner or can be indicated on a form sent to the new owner by the RO or the SA and which is designed to document his or her wishes in regard to continuing program participation.

In all cases of refusal to accept assignment, take all reasonable steps to ensure that beneficiaries under the care of the provider are aware of the prospective termination of the agreement. In this situation, there may be a period when the facility is not participating and beneficiaries must have sufficient time and opportunity to make other arrangements for care prior to the CHOW date.

After the CHOW has taken place, the RO acknowledges the refusal to accept assignment in a letter to the new owner, with copies to the SA and the FI. The RO completes a Form HCFA-2007 with the date the agreement is no longer in effect, noting that the termination is due to the new owner's refusal to accept assignment of the provider agreement.

It is the responsibility of a prospective purchaser of a Medicare provider to know that he/she can refuse to accept assignment of the provider agreement and that he/she should formally indicate his/her choice in that regard. If, however, the CHOW goes into effect without a refusal or acceptance of assignment on record, the RO assumes that the agreement has been automatically assigned to the new owner and completes processing of the CHOW.

If the new owner refuses to accept assignment after the date the CHOW has taken place, the RO should contact its regional attorney for guidance.

If a new owner refuses to accept assignment and also wishes to participate in the Medicare program, the RO first processes the refusal as indicated above and then treat the new owner as it would any new applicant to the program: obtain and process application documents, have the SA perform an initial survey and, if all requirements for participation are met, assign an effective date of participation based upon the applicable regulation. (See 42 CFR 489.13.)

B. Withdrawal After CHOW - Provider.--If, after a CHOW takes place, the RO receives notice that the new owner of a provider wished to withdraw from the program, the RO consults with the new owner to set a withdrawal date designed to protect the health care of program beneficiaries who may be patients of the provider. The RO sets a withdrawal date of up to 6 months beyond the provider's notice of intent to withdraw. Under these circumstances, the RO processes a complete CHOW notice and a withdrawal.

C. CHOW and Withdrawal - Supplier.--If the new owner of a supplier declines to participate, the RO negotiates a withdrawal date that does not disadvantage any program beneficiaries the supplier may be serving. The RO processes the supplier withdrawal as usual.

Expansion of Services

## 3220. CERTIFICATION OF ADDITIONAL SERVICES

Several categories of providers/suppliers require specific approval prior to becoming eligible to receive Medicare and Medicaid payment for services beyond those for which they were initially certified. The specific provider/supplier types affected by this requirement are:

- o HHAs;
- o RHCs; and
- o ESRD facilities.

During the initial survey and resurveys, the SA advises the provider/supplier to inform it promptly in writing when an additional service is contemplated, so that it can evaluate compliance with the pertinent CoPs or Conditions for Coverage. Do not accept oral requests. When the SA is notified of the addition by the provider/supplier or learns that a service has been added, it reviews applicable documentation and, as necessary, performs a survey of the new service promptly. The SA records the results on the appropriate survey report.

The only services of an HHA that when added would require a survey are OPT and speech therapy services. (See 42 CFR 484.38 and §3222.) This usually does not require an immediate survey, but can be surveyed at the time of the next standard survey.

A. Services In Compliance.--If a new survey is performed and the service meets the applicable Conditions, the SA recertifies the provider/supplier as continuing to meet the CoPs or Conditions for Coverage and complete Form HCFA-1539. It includes an explanation in Item 17 concerning the added service and an evaluation of the new service.

B. Services Not In Compliance (HHAs, RHCs, and ESRD Facilities).--If a new service does not meet the applicable Condition(s), the SA informs the provider/supplier that it must either come into compliance or stop providing the service to avoid termination action.

If the provider/supplier agrees to stop providing a service, the SA notes this action in its files and follows up within 60 days to ascertain whether the service has been discontinued. If the provider/supplier is unwilling to correct or stop providing the service, the SA initiates termination action.

## 3222. SPECIFIC REQUIREMENTS FOR EXPANSION OF SERVICES

A. HHA's Request To Provide OPT Services on Its Premises.--An HHA may provide OPT services on its premises as well as in patients' homes. The HHA providing services on its premises must meet and should be surveyed for compliance with 42 CFR s 485.723 and 485.727. These regulations do not apply to physical therapy services provided in patients' homes.

B. RHC's Request To Provide Visiting Nurse Services.--After the clinic is approved as an RHC, it may also seek approval to provide covered visiting nurse services. These services must be furnished by an RN, LPN, or licensed vocational nurse. (See 42 CFR s 405.2411, 405.2416, and 405.2417.)

When a request is received, the RO must determine whether there is a shortage of HHAs in the area. If there is an existing HHA furnishing services in the RHC area, the SA contacts the HHA for a statement of its ability or inability to adequately furnish nursing services in the area. In addition, the SA obtains information from the local or State health planning organization. The SA transmits the request and all pertinent documentation to the RO. The SA does not approve the visiting nurse services at this point.

If the RO determines that there is not a shortage of home health services for the area, authority to furnish visiting nursing services to homebound patients will be denied, and the RHC will be expected to refer its homebound patients to the HHA serving the area. The SA will receive a copy of the RO determination notice.

For purposes of this development, a "homebound individual" is one permanently or temporarily confined to his/her place of residence because of a medical or health condition. The individual may leave the place of residence infrequently and still be considered homebound. However, an individual in a hospital or long term care facility is not "homebound" for purposes of visiting nurse services.

If the RO determines that there is a shortage of home health services, it will request that the SA evaluate the qualifications of RHC personnel who are responsible for delivery of nursing services.

The SA completes the applicable sections of the Rural Health Clinic Survey Report (Form HCFA-30) for visiting nurse services and a written plan of care. The SA reviews records (plans of care and other appropriate records) to verify that such services are provided to homebound individuals and are furnished under written plans of care developed and signed by the supervising physician, nurse practitioner, physician assistant, or nurse midwife and reviewed by the supervising physician at least every 60 days. If the service has recently been implemented, it may be necessary for the SA to follow-up later to determine that the 60-day requirement is being observed.

When the above development has been completed and evaluated, the SA completes a supplementary certification for the visiting nurse service.

C. ESRD Facilities-Expansion In Number of Approved Stations.--Follow the procedure in §2274. (Also see Exhibit 27.)

## 3224. ADDITION OF SITES TO AN EXISTING PROVIDER

It is inherent in the provider certification process that a provider provide notification to HCFA of its proposal to expand its service area by adding a branch, satellite or extension location. The Medicare statute and applicable regulations are implicit that the proposed expanded service area meet the Conditions of Participtionthe same as the primary location that has signed the provider agreement or that has been assigned a provider number or both. In the absence of notification, HCFA has no way of determining whether the requirements critical to health and safety are met at the expanded location. For example, a hospice's request for satellite location may be denied because it cannot demonstrate how the hospice will assume administrtive and supervisory responsibility for the services provided at the expansion site. Moreover, there is no basis for a provider to bill Medicare for services provided by a site which has not been determined to meet applicable requirements of participation.

When an expansion request is received, before making a determination the RO considers the following:

o Whether the proposal meets Medicare statutory and regulatory requirements. For example, in the case of an HHA, does the proposed branch meet the definition of a branch office at 42 CFR 484.2? If it is possible to make a decision based on the provider's description of how it intends to operate, an onsite survey may not be necessary.

o If the proposal complies with State and local laws related to the particular type of provider/supplier; and,

o Whether Medicare reimbursement is affected by the proposal. For example, a hospital states that is has purchased a physicians' clinic that is now a part of the hospital. In such a case, input from the Division of Medicare and the fiscal intermediary will likely be necessary. While HCFA does not dictate to a provider how it should operate its business, the provider does have to comply with Medicare requirements. Whenever an entity can meet the requirements of two different categories; e.g., subunit and independent home health agency, it is generally HCFA's policy to designate the category for which there is the least potential to increase Medicare costs. If a proposed branch is in an area that would receive a different payment rate than the parent HHA, it could be found to be in a different geographic area and determined not to be a branch.

Although legal authority exists for conducting a survey, a survey may not be necessary because the provider furnishes the RO with sufficient information to make a determination about its proposed expansion either at the time of its initial request or subsequently. If the RO believes a survey is required, but the SA is unable to conduct a survey within a reasonable period of time, the RO may take one of the following actions:

o Make a determination based on the expansion information provided by the provider and inform the provider of the decision; and

o Inform the provider that a survey will be necessary and that it should not bill Medicare for services provided at the proposed expansion location until the survey is conducted and a determination is made.

In the absense of notification of an expansion, HCFA has the authority to deny bills for services furnished at the expanded site. When notification is received of a proposed expansion, the RO should inform the provider of whether the expanded site meets applicable requirements. The fiscal intermediary should be notified of the RO's decision.

## Validation Surveys of Accredited Providers and Suppliers

### 3240. VALIDATION SURVEYS - CITATIONS AND GENERAL DESCRIPTION

An accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program whose requirements have been approved by HCFA as equivalent to the Federal requirements. An accredited provider or supplier will be deemed to meet the Medicare Conditions if the provider or supplier:

- Authorizes the accreditation organization to release to HCFA and the SA a copy of its most current accreditation survey, with any information related to the survey that HCFA may require (including corrective action plans);
- Permits the validation survey to take place; and
- Authorizes you to monitor the correction of any deficiencies found during the validation survey.

Any provider or supplier that has been accredited prior to HCFA's approval of the national accreditation program will not be deemed to meet Medicare Conditions.

NOTE: For the purposes of this section, the term "Condition" refers to any Condition of Participation or Coverage. (See Chapter VI which discusses validation surveys for accredited laboratories.)

Sections 1864(c) and 1865 of the Act provide the basis for conducting validation surveys of accredited hospitals and establishes the basic framework for conducting validation surveys of most all accredited providers and suppliers. Regulations authorizing such surveys are found in 42 CFR 488.7. HCFA may require a survey of an accredited provider or supplier to validate the accreditation organization's process. These surveys will be conducted on a representative sample basis (i.e., sample survey), or in response to a substantial allegation of noncompliance (i.e., complaint survey).

A representative sample validation survey is comprehensive and addresses all Medicare Conditions, that are deemed to meet the Medicare conditions or is focused on a specific Condition(s). A substantial allegation/complaint survey focuses on any Condition HCFA determines is related to the complaint.

If a provider or supplier selected for a validation survey fails to comply with validation survey protocol, it will no longer be deemed to meet the Medicare Conditions. It will be subject to full review by the SA and may have its provider agreement terminated for failure to meet the Medicare conditions.

### 3242. OBJECTIVE OF VALIDATION SURVEYS

Validation surveys are intended to develop a reasonable estimate of an accreditation organization's performance and to assess the ongoing acceptability of accreditation as an alternative to routine survey and certification activities. Validation surveys are to be conducted in accordance with the survey protocol for the facility type being surveyed to assure a fair basis for comparing the effectiveness of accreditation programs.

## 3243. SAMPLE VALIDATION SURVEYS OF ACCREDITED HOSPITALS

A. General.--The survey process is designed to evaluate the premise that a hospital that receives JCAHO or AOA accreditation is, in fact, meeting Medicare health and safety requirements. The SA conducts validation surveys of accredited hospitals in strict accordance with established procedures to ensure a fair basis for evaluating the effectiveness of approved accreditation organizations.

CO selects a representative sample of accredited hospitals to be validated and forwards this listing to the ROs. The validation survey covers all the Conditions that are deemed to be met by virture of accreditation of JCAHO or AOA accreditation. It does not include utilization review (UR), swing-bed, or the special medical record or staffing requirements for psychiatric hospitals. However, if these Conditions need to be surveyed by the SA within the next 60 days, they may be included to minimize the number of onsite visits ot the hospital.

The CO listing for the hospital sample validation program may include conditionally accredited hospitals, as well as accredited hospitals at various times in their accreditation cycle. CO will specify the type of survey to be conducted for these hospitals in the memorandum to the RO accompanying the listing. These surveys must be completed within 60 days of the date of the request to the SA.

B. Setting Up Validation Survey.--The RO sends a copy of Form HCFA-2808, Request for Validation of Accreditation Survey, with item 6 checked to notify the SA that a sample validation survey is to be conducted.

## 3244. SA PREPARTION FOR VALIDATION SURVEY OF A HOSPITAL

A validation survey may either be a representative sample or substantial allegation/complaint survey and is initiated when the RO sends the SA a Request for Validation of Accreditation Survey, Form HCFA-2802 (Exhibit 33). Item 6 is checked to indicate that the survey is a representative sample validation survey, or Item 7 is checked to indicate that the survey is a substantial allegation/complaint survey. The SA schedules the survey within 60 days of the accreditation survey or 60 days following the receipt of the RO request, whichever is earlier.

A. Unannounced Surveys.--A complaint survey is always unannounced. HCFA personnel may be present during the survey to provide assistance and assure nationwide uniformity and validity.

B. Announced Surveys.--The SA contacts the [hospital] administrator or charge person by telephone as early as possible to schedule the sample validation survey and follows up with a letter to confirm the date (see Exhibit 35 and 37), enclosing a Hospital Request for Certification, Form HCFA-1514 (see Exhibit 36) for hospitals. This is required to obtain authorization from the hospital for the accreditation organization to release to HCFA its most recent survey findings and to provide the SA with current information which is necessary to properly schedule a survey. The SA forwards a copy of the letter to the RO and to the accreditation organization. HCFA personnel may be present during the survey to provide assistance and to help assure validity.

The SA assigns surveyors who normally conduct surveys of nonaccredited providers. The SA completes the survey in approximately the same timeframe required for a nonaccredited hospital of similar size. All team members are required to survey a provider or supplier concurrently, even if this is not the SA's normal procedure. This applies to representatives of the fire marshall's office who conduct the LSC survey as well as to all SA personnel.

## 3246. AUTHORIZATION FOR RELEASE OF HOSPITAL ACCREDITATION SURVEY

Before beginning the survey, the SA requests that the administrator complete Form HCFA-1514 for hospitals. (See Exhibit 36.) This form authorizes release of the hospital's most recent accreditation survey. If the administrator refuses to complete the form, the SA surveyor explains the validation survey protocol procedure in greater detail. If a signature cannot be obtained, the SA documents its efforts, notifies the RO, and advises the hospital to contact its accreditation organization to further clarify the procedure.

## 3248. HOSPITAL REFUSAL TO PERMIT VALIDATION SURVEY

If, after efforts have been made to explain the validation survey protocol procedure, the hospital continues to refuse to authorize the validation survey to take place, and/or the SA to monitor the correction of any deficiencies found through the validation survey, the SA informs the hospital that failure to comply with the "deemed" status requirements is sufficient basis for transfer of survey responsibility to the SA for Medicare participation. The SA informs the hospital that its "deemed" status will be removed and may also be subject to termination from the Medicare program (and, where applicable, the Medicaid program) if it is found not to be in compliance with Medicare Conditions. If the hospital continues to refuse to permit the validation survey, the SA notifies the RO. The SA informs the RO of all efforts made to encourage compliance.

An accredited hospital may again be deemed to meet the applicable Medicare Conditions when:

- It withdraws any prior refusal to authorize its accreditation organization to release a copy of the hospital's current accreditation survey;
- It withdraws any prior refusal to allow a validation survey; and
- It meets all the applicable Medicare Conditions. (If the SA determines that an accredited facility meets the LSC standard by virtue of a PoC, continue to monitor the facility until it is in compliance with the LSC standard.)

## 3250. SA CONDUCTING SAMPLE VALIDATION SURVEYS FOR HOSPITALS

The SA conducts sample validation surveys with complete objectivity so that there is a fair basis for evaluating the effectiveness of the accreditation process. To permit an independent compliance decision, the SA will not be provided with a copy of the accreditation organization's findings. The SA conducts the survey in accordance with the survey protocol for hospitals. The SA uses the appropriate survey forms noted on the List of Documents in Certification Packet (see Exhibit 63) and the interpretive guidelines when performing the survey. The SA conducts the survey as if the hospital was nonaccredited for all those CoPs that are deemed met by virtue of accreditation, with the following important differences:

- Do not survey those Conditions not deemed met, for example, UR, special staffing and special medical records for psychiatric hospitals, and hospital providers of LTC services ("swing-bed"). However, if the SA intends to schedule the survey of these Conditions within 60 days of the validation survey, the two may be conducted concurrently. The SA advises the hospital of this by letter at the time of notification of the validation survey. The SA provides the RO with a copy of these survey findings with the validation survey materials.

In most States, an engineer or other fire safety specialist surveys for compliance with the LSC standards and others survey the remaining standards in the Physical Environment Condition. Failure to comply with the LSC (if applicable) will place the provider or supplier under SA jurisdiction. The SA completes Form HCFA-670, Survey Team Composition and Workload Report, at the conclusion of any survey conducted.

## 3252. SA FORWARDING SAMPLE VALIDATION RECORDS TO RO

The SA submits the appropriate information as specified on the List of Documents in Certification Packet (see Exhibit 63) to the RO or through an update to the OSCAR database within 30 days of completing the survey. In cases where immediate jeopardy exists, the SA submits all the appropriate information specified on the List of Documents in Certification Packet to the RO, or through an update to the OSCAR database, within 2 days of completing the survey. The SA also completes the Survey Team Composition and Workload Report (Form HCFA-670).

If the hospital chooses not to submit a PoC when deficiencies are found that are not condition level, the SA reports any known information about the hospital's efforts to correct deficiencies.

## 3254. RO ACTIONS FOLLOWING SAMPLE VALIDATION SURVEY

Upon receipt of survey materials, the RO analyzes and considers the SA recommendations. The RO takes necessary action within 30 days and inputs the information into OSCAR within 60 days of the compliance decision date.

A. Hospital Found in Compliance Following Sample Validation Survey.--If the hospital is in compliance with all Conditions, the RO notifies the hospital and sends a copy to the SA. (See Exhibit 194.)

B. Hospital Found Not In Compliance With One or More Conditions Following Sample Validation Survey and Noncompliance Constitutes Immediate Jeopardy.--If it is documented that an immediate jeopardy exists to patient health and safety, the RO follows the adverse action procedures (see §3010), and notifies the hospital and the SA by overnight mail (or facsimile) of the action being taken. (See Exhibit 195). Process the certification as any certification of noncompliance of an inaccredited hospital.

If the SA informs the RO that the hospital has made a credible allegation of compliance or correction of the immediate jeopardy situation before the adverse action is taken or completed, the RO authorizes the SA to conduct a revisit, if necessary, to verify the correction.

C. Deficiencies That Do Not Pose Immediate Jeopardy.--If it it documented that the hospital is out of compliance with one or more Conditions, but the deficiencies do not pose immediate jeopardy to patient health and safety, the FO follows the adverse action procedures . (See §3012.) The RO notifies the hospital that it has been found out of compliance with a Condition(s) and will be placed under SA monitoring (Exhibit 196). The RO informs the hospital that a Plan of Correction (PoC) for all cited deficiencies must be obtained if participation in the Medicare program is to continue. A copy of the letter is provided to the accreditation organization and the SA.

The hospital continues to be accredited by its accreditation organization and is still permitted to participate in the Medicare/Medicaid programs while correcting the deficiencies. However, it is subject to the same requirements, survey and enforcement procedures applied to nonaccredited hospitals found out of compliance following a survey. The hospital is monitored by the SA until it reaches compliance with all Conditions or it is terminated from the Medicare program, and where applicable, the Medicaid program.

D. Hospital Request for Review of Findings of Noncompliance.--The hospital has 15 days to request an informal review of the survey findings. If the hospital disagrees with the noncompliance decision, the RO examines all available facts, including any additional infomraiton and recommendations submitted by the SA after completion of the survey. If the RO reverses the noncompliance decision, it notifies the hospital in accordance with suggested language in Exhibit 194. If the noncompliance decision is affirmed, the RO sends a written notification of the decision to the hospital and the SA.

E. Plans of Correction.--If the RO concurs with the SA's recommendation of an acceptable Plan of Correction, the RO sends a written notification to the hospital (Exhibit 197).

Where the SA has found the Plan of Correction unacceptable and the RO concurs with the SA's recommendation, it notifies the hospital in writing.

F. Termination.--HCFA will terminate a hospital if it does not submit an acceptable Plan of Correction, or if after a reasonable period of time, it does not correct the Conditions that have been determined to be noncompliant. The RO obtains copies of the latest survey material before proceeding with termination procedures.

G. Compliance With All Conditions After Correction of Deficiencies.--When an accredited hospital is determined to be in compliance with all Conditions, the RO notifies the hospital accordingly (and where applicable, the SMA). The RO informs the SA, in writing, to cease monitoring activities. Revisits by the SA are never authorized after an accredited hospital has been notified that it is in compliance with all applicable Medicare Conditions.

## 3256. RO REFERRAL OF DOCUMENTATION TO ACCREDITATION ORGANIZATIONS

A. Documents To Be Forwarded to Accreditation Organizations.--The RO forwards the following information to the hospital's accreditation organization:

- o A copy of Form HCFA-2802;
- o A copy of the letter with the ROs decision of compliance or noncompliance, along with Form HCFA-2567, within 60 days of completion of the survey; and,
- o A copy of any subsequent notification (e.g., imposition of an adverse action) at the time of preparation.

Forward copies to:

Joint Commission on Accreditation of Healthcare Organizations
Attn: Vice President, Government Relations
One Renaissance Boulevard
Oakbrook Terrace, IL 60181

or

American Osteopathic Association
Attn: Director, Division of Healthcare Facilities Accreditation
142 East Ontario
Chicago, IL 60611

## 3257. REINSTATEMENT TO ACCREDITATION ORGANIZATION JURISDICTION

A. Hospital Under SA Monitoring.--A hospital which has been under SA montitoring is returned to full accreditation ("deemed") status when it is determined that:

- o All the Conditions, including the LSC standard, are met.

When the hospital is returned to the accreditation organization's jurisdiction, the RO notifies the provider or supplier in writing. (See Exhibit 198.) The RO forwards a completed copy of the Certification and Transmittal, Form HCFA-1539, to the SA. Revisits are never authorized after an accredited facility is notified that is is in compliance with all applicable Medicare Conditions.

## Investigation of Complaints Against Accredited Providers or Suppliers

### 3260. BASIS FOR ACCREDITED PROVIDER OR SUPPLIER SUBSTANTIAL ALLEGATION/COMPLAINT INVESTIGATION

Sections 1864(c) and 1865 of the Act provides the basis for conducting complaint surveys of accredited hospitals and establishes the basic framework of complaint surveys for virtually all other accredited providers and suppliers. Regulations authorizing such surveys are found in 42 CFR 488.7(a)(2). The SA should refer to the RO all allegations against JCAHO or AOA accredited hospitals concerning violations of 42 CFR 489.24 or the related provisions of CFR 42 Part 489.20 (Responsibilities of Medicare Participating Hospitals in Emergency Cases), poor quality of care or other indications of noncompliance with CoPs.

A substantial allegation of noncompliance refers to a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of patients, and raises doubts as to a provider's or supplier's compliance with one or more Conditions.

If the RO learns of a substantial allegation of noncompliance concerning an accredited provider or supplier, the RO will review the complaint, and if it relates to the provider's or supplier's compliance with one or more Conditions, it will refer the complaint to the SA for investigation or will conduct its own investigation. If the allegation was received formally by the RO, the RO will send a letter to the complainant, acknowledging the complaint and advising that an appropriate investigation will be initiated. The RO will also be responsible for any follow-up letter, if applicable, to advise the complainant of the results of the investigation and of any correction action taken.

If the SA receives a substantial allegation of noncompliance directly from a complainant about an accredited provider or supplier, it acknowledges receipt of the complaint, and advises the complainant that an appropriate investigation will be initiated if one is warranted. The SA forwards a copy of the acknowledgement letter and the complaint to the RO. The SA is not to conduct the complaint survey unless authorized by the RO. Although an allegation may not warrant investigation, the RO sends a copy to the accreditation organization if the allegation pertained to any survey and enforcement issues. The SA may have authority through State law or other jurisdiction to pursue some aspects of the allegations on its own. However, the SA should advise the RO prior to instituting any State action against an accredited facility. The SA includes copies of the pertinent investigative report with the complaint referred to the RO. The SA logs the complaint as explained in §3281.B. In this case where the SA has acknowledged receipt of the complaint, it is not necessary for the RO to send an acknowledgement. However, the RO is responsible for advising the complainant of the results of the investigation.

If the SA or the RO determines that a complaint refers to a question or issue that is clearly beyond the purview of the Medicare survey and enforcement program, the SA should advise the complainant of the limits of the SA or RO involvement and, if appropriate, mention a possible alternative source of assistance or refer the complaint to the appropriate agency.

### 3262. RO DIRECTION OF ACCREDITED HOSPITAL COMPLAINT INVESTIGATION

If the RO determines that a survey should be performed, the RO prepares a Request for Validation of Accreditation Survey, Form HCFA-2802 (see Exhibit 33), and forwards it to the SA with a copy of the allegation(s). (The RO may direct the SA to investigate specific areas of the hospital's operation related to the anti-dumping provisions where there is an indication of noncompliance with

42 CFR Part 489.24, the related requirements of 489.20, and/or a CoP. The SA's responsibility is to investigate whether the regulations are violated and/or whether the affected Conditions are met.) The SA date-stamps the form with the date of receipt. The RO will check Item 5 to indicate that the facility is not to be notified in advance of the survey. Item 7 of Form HCFA-2802 identifies the Conditions and standards related to the allegation to be investigated. The RO may, in addition, identify other related areas for SA review during the survey. When an investigation can be conducted through letter or telephone (e.g., personnel credentials), those means are to be used. If the SA receives the complaint directly, it makes an initial judgement for handling the complaint and forward to the RO.

Obtain the following information for every allegation:

- o Complainant's name and address (unless complainant requests anonymity);
- o Hospital's name and address; and
- o Description of problem, including names, places, and dates.

The SA uses whatever form or format the SA is already using for recording or summarizing an allegation. Form HCFA-562 (Exhibit 75) is not intended for this purpose. The SA investigates a complaint within 2 days of receipt of Form HCFA-2802 from the RO if the RO determines that the complaint involves a potential immediate jeopardy to patient health and safety. Otherwise, the RO directs you to investigate non-immediate jeopardy complaints within 45 days.

## 3264. SA CONDUCTING AN ACCREDITED HOSPITAL COMPLAINT VALIDATION SURVEY

Complaint validation surveys are always unannounced. The SA conducts the complaint validation survey of an accredited hospital based on a substantial allegation of noncompliance. (If the complaint alleges a violation of 42 CFR 489.24, or the related provisions of 42 CFR 489.20, follow the procedures in §§3400-3412.) A substantial allegation of noncompliance may be a complaint from a variety of sources. The complaint need not be formal, be directed toward HCFA or the SA, or be a result of first-hand experience. The SA assigns surveyors who normally conduct surveys of nonaccredited hospitals. The SA may request assistance from the RO if it is unable to conduct the investigation within a reasonable timeframe because of a shortage of specialist surveyors.

Although an allegation may not warrant investigation, the RO sends a copy to the accreditation organization if the allegation pertained to any survey and enforcement issues.

In most States, an engineer or other fire safety specialist surveys for compliance with the LSC standard and others survey the remaining standards in the Physical Environment Condition. Since failure to comply with the LSC (if applicable) will place the hospital under SA jurisdiction, it is not necessary to survey the other standards in the physical envirnment condition. If a full survey is necessary, survey the remainder of Physical Environment along with the other Conditions.

If a hospital refuses to permit a complaint survey, the SA follows the procedures in §3248.

Before beginning the complaint survey, the SA requests that the administrator complete the appropriate Request for Certification (Form HCFA-1514 for hospitals). The SA does not disclose the identity of complainants, and does not involve them in the investigation unless specifically directed by the RO. The SA conducts the complaint survey in accordance with the survey protocol for hospitals. The SA uses the appropriate survey forms noted on the List of Documents in Certification Packet (see Exhibit 63) and the interpretative guidelines when performing the survey. The SA only surveys the Conditions related to the complaint.

If the SA is unable to substantiate the complaint, it concludes the inspection promptly without an exit interview but it informs the administrator of its findings. The SA completes Form HCFA-2567 with the statement "No deficiencies found." If the SA substantiates the complaint and/or finds Condition level deficiencies during the course of the complaint investigation, it conducts an exit conference.

At the exit conference, the SA informs the hospital of any deficiencies found. If the deficiencies do not pose an immediate jeopardy to patients' health and safety, the SA prepares a Form HCFA-2567 and requests that the hospital submit a PoC to it. The SA informs the hospital that Form HCFA-2567 will be made available to the public under the disclosure of survey information provisions. The SA indicates that Form HCFA-2567 will be forwarded to the hospital within 10 days and that the PoC must be returned to it within 10 days. The SA does not monitor the correction of deficiencies unless requested to do so by the RO.

If the deficiencies pose an immediate jeopardy, the SA prepares Form HCFA-2567 and notifies the RO for immediate action. The SA forwards Form HCFA-2567 to the RO within 2 days following the finding of an immediate jeopardy situation.

The SA completes Form HCFA-670 at the conclusion of any survey conducted.

## 3266. FORWARDING INVESTIGATION REPORT TO RO

The SA submits the appropriate information as specified in Exhibit 63 to the RO or through an update to the OSCAR database within 30 days of completing the survey. In cases where immediate jeopardy exists, submit all the appropriate information specified in Exhibit 63 to the RO within 2 days of completing the survey. The SA includes Form HCFA-670, Survey Team Composition and Workload Report.

If the hospital chooses not to submit a PoC when deficiencies are found below the Condition level, the SA reports any known information about the hospital's effort to correct deficiencies.

## 3268. ACCREDITED HOSPITAL FOUND IN COMPLIANCE FOLLOWING COMPLAINT VALIDATION SURVEY

If, after review of the documentation, the RO determines that the accredited hospital is in compliance with all Medicare Conditions, it officially notifies the hospital (Exhibit 194) and forwards a copy of the letter to the SA and the accreditation organization. The notification letter advises that the accreditation organization may contact the hospital about the correction of any deficiencies below the Condition-level. The SA does not conduct follow-up visits.

## 3270. ACCREDITED HOSPITAL FOUND NOT IN COMPLIANCE FOLLOWING COMPLAINT VALIDATION SURVEY

If there are deficiencies that pose an immediate jeopardy to patient health and safety, the provider or supplier may be subject to termination by the RO. (See §§3010 and 3274.) The RO officially notifies the hospital (Exhibit 195) and forwards a copy of the letter to the SA and the accreditation organization.

Should the immediate jeopardy situation be corrected before the adverse action is taken or completed, the letter advises the hospital that the SA will conduct a revisit to inspect all remaining Conditions.

If the RO determines that the hospital is out of compliance with one or more Conditions, but they do not pose an immediate jeopardy to patient health and safety, the RO notifies the hospital that it is out of compliance and will be placed under SA monitoring jurisdiction (Exhibit 199). A copy of the letter is provided to the accreditation organization. The SA completes a full survey and requires the hospital to submit a PoC. The hospital continues to be accredited by its accreditation organization but it is subject to the same requirements, survey, and enforcement procedures applied to a nonaccredited hospital found out of compliance following a survey (see §3012). The hospital is monitored until it reaches Condition-level compliance or it is terminated from the Medicare program and where applicable, the Medicaid program.

## 3272. REINSTATEMENT TO ACCREDITATION ORGANIZATION JURISDICTION

A. Hospital Under SA Monitoring.--A hospital which has been under SA monitoring is returned to full accreditation status when the RO has determined that:

- The hospitals's major deficiencies have been corrected; and
- All the Conditions, including the LSC standard, are met.

B. Hospital Refused To Allow Survey.--A hospital found out of compliance because of its refusal to allow a survey is returned to the accreditation organization's jurisdiction when:

- The hospital permits the validation survey to be conducted; and
- The hospital withdraws any prior refusal to authorize its accreditation organization to release a copy of its current accreditation survey.

## 3274. TERMINATION OF ACCREDITED HOSPITAL

Where deficiencies identified pose an immediate and serious threat to patient health or safety, SA monitoring begins immediately, and the 23 day termination procedures described in §3010 will apply.

Where there is noncompliance with a CoP but the deficiencies are not an immediate and serious threat, the accredited hospital must be first placed under SA monitoring before further SA action can be taken. Thus, it may frequently take longer than 90 days from the first documentation of noncompliance to the decision to terminate. Where the first full survey carried out under SA monitoring confirms that a Condition is still out of compliance, the RO applies the termination procedures described in §3012, and give the hospital a reasonable time to achieve compliance (up to 90 days) in accordance with an approved PoC. As described in Step 3 of §3012, if the hospital alleges corrections have been or will be made timely, the SA conducts an appropriately timed revisit to determine whether compliance or acceptable progress has been achieved. If neither has occurred, the SA certifies noncompliance and forwards the certification and supporting documentation to the RO. (See Step 4 of §3012.)

## 3276. INVESTIGATING COMPLAINTS INVOLVING ESRD SERVICES PROVIDED BY ACCREDITED HOSPITALS

Most of the hospitals participating in the ESRD program are accredited by JCAHO or AOA. "Deemed status" applies only to the hospital's approval as a provider, not to its status as a supplier of ESRD transplantation or dialysis services. The SA investigates all complaints and allegations related solely to ESRD services since ESRD services fall outside the purview of accreditation. Follow the procedures in §3280ff.

## Investigation of Complaints Against Other Than Accredited Providers and Suppliers

### 3280. SA RESPONSIBILITIES FOR GENERAL, CERTIFICATION-RELATED COMPLAINTS

An allegation is an assertion of improper care or treatment against a Medicare, Medicaid or CLIA facility that could result in the citation of a Federal deficiency. Guidelines for handling the other special types of complaints, i.e., those involving blood transfusion-related fatalities, HIV-infected persons, CLIA laboratories, ESRD services provided by a hospital or accredited hospitals are discussed in §§3260 through 3276, 3298, 6280 and 7700.

All the procedures in this section are mandatory when complaints involve Medicare, Medicaid, or CLIA facilities. The SA may, however, adopt more stringent guidelines. It is the SA's responsibility to ensure that a Medicare/Medicaid Complaint Form (Form HCFA-562) (Exhibit 75) is completed for any substantiated or unsubstantiated allegations that are investigated by means of an onsite survey, and that these records are entered into the OSCAR System Complaint Subsystem. (See §3282.) The Form HCFA 562 is also used for CLIA complaints.

Investigation and resolution of complaints is a critical certification activity. HCFA, the SMA, and the SA are responsible for ensuring that participating facilities continually meet Medicare and Medicaid requirements. This requires prompt review by the SA and, if necessary, on-site investigation of reports alleging noncompliance and informing the RO and/or the SMA any time certification requirements are found to be out of compliance. The SA responsibility cannot be delegated.

### 3281. SA PROCESSING GENERAL, CERTIFICATION-RELATED COMPLAINTS

The following procedures describe each step in the processing of a complaint from receipt to closeout. As these activities are likely to cut across organizational lines, The SA establishes clear cut accountability for each aspect and a focal coordinating/controlling responsibility to assure timely and appropriate action.

A. Collection.--Complaints may come directly to the SA from individuals receiving services or their representatives. They may also be referred from the RO or other State, Federal, or private organizations. Allegations about Medicare/Medicaid/CLIA facilities originate with a variety of State and local agencies. The SA must ensure that all of those organizations are aware of the SA's authority and responsibilities regarding complaints, and that they refer all allegations to the SA office.

The SA obtains the following information for every allegation:

- Complainant's name, address, and phone number (unless complainant requests anonymity);
- Patient/resident's Medicare number, if applicable;
- Facility's name and address; and
- Description of problem, including names, places, dates.

B. Control.--Immediately after receipt, the SA establishes a file for the allegation. A control system should be used to facilitate tracking and control of the allegation until it is entered into the OSCAR Complaint Subsystem.

C. Acknowledgement (If Complainant Is Known).--The SA promptly notifies the complainant in writing or with a telephone call that the complaint is being investigated, unless the RO or SMA that originally received the allegation has already done so. The SA does not delay acknowledgement pending an investigation unless the investigation will take place within three working days. The SA must take appropriate precautions to protect the complainant's anonymity and privacy. (See §3282.E.) The SA maintains a copy of this notification with the complaint documentation.

D. Evaluation.--

1. Referral.--The SA evaluates any complaint to determine whether it should be retained in the SA for investigation or forwarded to the RO or other appropriate authority (e.g., for cases of billing complaints, the carrier or FI. Other concerns may be appropriately handled by other State agencies or authorities.) Refer allegations involving the following to the RO within 3 working days:

- o Accredited hospitals. (See §3260 for procedures);
- o Accredited HHAs;
- o Federal facilities;
- o Christian Science sanitoria;
- o CLIA laboratories holding a certificate of accreditation. (See Chapter 6.)
- o CLIA-exempt laboratory. (See Chapter 6.);
- o Blood transfusion-related fatalities. (See Chapter 6.);
- o Over-utilization or inappropriate utilization of services (PRO jurisdiction);
- o Civil rights violations; or
- o Medicare/Medicaid fraud.

Refer all dumping complaints to the RO immediately.

2. Notice.--Even if referral is not necessary, the SA considers whether any special notification is appropriate. If a complaint is especially significant and/or sensitive or is attracting broad public or media attention, the SA informs the RO immediately. Additionally, the SA needs to consider any other early notice requirements prescribed by other State or Federal polices or interagency agreements.

E. Investigation.--

1. Scheduling Investigation.--If the allegation involves an immediate and serious threat to patient health and safety (see §3010), the SA investigates within 2 working days of receipt. Otherwise, follow SA existing procedures for prioritizing and investigating certification-related complaints.

2. Conducting Investigation.--

a. General Procedures.--Complaint surveys are never announced. The SA assigns the investigation to an individual(s) with expertise in the specific areas involved in the allegation.

When visiting a facility to investigate a complaint, the SA explains the reason for the visit and avoid any impression that a predetermination has been made as to the validity of the allegation. The SA does not divulge the complainant's identity.

The SA uses the appropriate survey report form (SRF) and interpretive guidelines for the facility. The SA conducts a partial survey or an abbreviated survey for SNFs/NFs focusing on the specific regulatory requirements related to the allegation. The SA reviews appropriate samples of residents, rooms, records, or services, as necessary, to assess compliance with applicable requirements (see Chapter 7). If, based on an initial assessment or other observations, significant problems are identified, the SA expands the scope of review as necessary to determine compliance or noncompliance. Generally, it is not necessary to review records and information from more than 1 year ago. However, the SA is not precluded from doing so if concerns identified during the investigation indicate it is necessary in order to determine current compliance.

Upon completion of the survey, the SA makes the appropriate portions of the SRF part of the complaint record. It becomes the basis for completion of Form HCFA-2567.

A complaint record may be one of four types:

- o Substantiated with deficiencies;
- o Substantiated with no deficiencies;
- o Unsubstantiated with unrelated deficiencies; or
- o Unsubstantiated with no deficiencies.

Substantiated with deficiencies and unsubstantiated with unrelated deficiencies are complaint records in which Federal deficiency(ies) are cited by the surveyor as a result of the investigation. Substantiated with no deficiencies and unsubstantiated with no deficiencies are complaint records in which Federal deficiencies are not cited by the surveyor as a result of the investigation. Substantiated with deficiencies means one or more of the allegations reported are verified and deficiencies were cited that are related to the allegations being investigated. Substantiated with no deficiencies means that one or more of the allegations reported occurred and is verified, but the allegations were corrected prior to the complaint investigation. Therefore, no deficiencies are cited. Unsubstantiated with unrelated deficiencies means that none of the allegations reported was verified, but deficiencies were observed and cited in other areas that are not related to the original allegations being investigated. Unsubstantiated with no deficiencies means that none of the allegations were verified and no deficiencies are cited. For CLIA complaints, see Chapter 6.

If a complaint record has deficiencies cited, the SA indicates all deficiencies on a Form HCFA-2567 and obtain a PoC, if appropriate. (See §2728.) The completed Form HCFA-2567 must be made a part of the complaint record.

b. Investigating Allegations of Substandard Patient Care.--When investigating allegations of substandard patient care, the SA evaluates not only the care furnished to individuals directly involved in the allegation, but also the institution's patterns of related care. The following is a suggested investigative approach oriented to health care. The SA should modify its approach as appropriate for other modes of treatment. Substandard patient care should not be confused with substandard quality of care for SNFs/NFs (see Chapter 7).

(1) Records and Record Maintenance.--The SA reviews a sample of individual records in relation to care plans and the consolidated patient records that are used by the nursing staff for evaluating care needs. In performing this review, the SA looks for consistency of data on the physician's order sheet or progress notes, care plans, and cardex data.

The SA examines the facility's staffing charts for the time in question and may use payroll and patient records to confirm the actual presence of assigned staff on scheduled shifts.

If applicable, the SA reviews the sufficiency of physician supervision of patient care, including whether written or oral orders are countersigned by the attending physician. Frequently, oral orders identify situations in which physicians are not visiting the patients as frequently as required in the CoPs.

When a complaint investigation involves reviewing a SNF's or NF's pharmaceutical review practices, the SA should follow the procedures in Appendix N. If appropriate to the level of care, the SA reviews records maintained by the nursing staff to identify administration of medication and performance of treatment, verifying them against the physician order sheet, nursing care plan, and nursing notes data. The SA identifies and records practices used in identifying cancellation or addition of a particular drug or treatment.

(2) Information from Nursing Personnel.--Depending on the nature of the complaint, the SA interviews nursing personnel about the availability of needed supplies and equipment, the procedures for scheduling patients for diagnostic procedures or treatment, and procedures for ordering and securing special diets.

(3) Documenting Findings.--The SA records findings on the SRF and explain in the remarks section how the evaluation of the quality of care was made.

(4) Assessment of Questionable Services.--The SA does not attempt to make a decision on the appropriateness of surgical or therapeutic-diagnostic services provided to a specific patient or group of patients.

If the SA receives an allegation that a facility is providing improper or inappropriate surgical, therapeutic, or diagnostic services, it refers the complaint to the RO. The RO will forward it to the PRO or appropriate regulatory agency for investigation.

F. Post-Survey Certification Actions.--Following investigation, the SA records any findings on Form HCFA-2567 and provide it to the facility per regular certification procedures. The SA requests a PoC for any uncorrected deficiencies including a deficiency of the LSC requirement which is a part of the Physical Environment CoP. (See §2728.)

Any subsequent certification actions depend on the nature of any deficiencies cited and the facility's willingness or ability to correct them.

When Federal deficiencies are identified, the SA initiates certification actions as follows:

1. Immediate and Serious Threat To Patient Health and Safety.--The SA certifies noncompliance and initiate expedited termination procedures. (See §3010.) (See §§7301 and 7307 for SNFs/NFs.)

2. CoP/Condition For Coverage Not Met (No Immediate and Serious Threat).--The SA certifies noncompliance and initiate procedures to recommend termination under §3012. (See §3005 for Medicaid providers and §§7301 and 7310 for SNFs/NFs.)

3. Physical Environment Condition Not Met For Failure To Meet LSC (No Immediate and Serious Threat In Nonaccredited Hospitals).--Certify noncompliance and initiate procedures as provided for nonaccredited hospitals. (See §3012.) (Also see §§7301 and 7310 for SNFs/NFs and §2480 for LSC waivers.)

4. All Conditions Met - Facility Unable or Unwilling To Provide Acceptable PoC For Other Deficiencies.--A facility with deficiencies may not participate without an acceptable PoC. If it is unable to provide such a plan within a reasonable time (not more than 45 days, the SA certifies noncompliance and forward all related supporting documentation to the RO. (See Chapter 7 for SNFs/NFs.)

A facility has a right to refuse to submit a PoC if it believes it has enough evidence to show that a deficiency is invalid. The SA (and/or the RO) examines the documentation presented by a facility that a deficiency did not exist and reconsider the deficiency determination. If necessary, the SA has the documentation reviewed by an individual who was not involved in making the original determination. If a deficiency did not exist, the SA removes the citation from the Form HCFA-2567. If it is determined that the evidence indicates a deficiency, the SA explains the rationale to the facility and requests submission of a PoC.

5. All Conditions Met - Facility Provides Acceptable PoC For Other Deficiencies.--The SA certifies compliance based upon an acceptable PoC and assemble documentation for RO review.

6. No Uncorrected Deficiencies.--No certification action is required.

G. Reporting.--Since the RO or SMA is obligated to formally determine whether to continue or terminate participation based upon the SA certification, the SA should make all necessary certification documents available to them. For each complaint investigated, the SA completes Form HCFA-562 (see Exhibit 75) and enters the record into the OSCAR Complaint Subsystem. When deficiencies are cited, the SA completes Form HCFA-562 (Parts I and II) and Form HCFA-2567 and forwards them to the RO or the SMA, as appropriate. When deficiencies are not cited, the SA completes Form HCFA-562 (Parts I and II, with the exception of Item #15). In this situation, Form HCFA-562 is not forwarded to the RO or the SMA, but enter it into the OSCAR Complaint Subsystem. The SA does not use Form HCFA-562 for blood-transfusion fatality complaints. (See Chapter 6 for laboratories.) Follow the SMA and SA procedure for title XIX facilities.

Specific SA post-investigation reporting requirements are as follows:

1. SA Routine Reporting To RO or SMA (Complaints With Deficiencies).--The SA reporting requirements which follow apply to complaint records with deficiencies cited that involve Medicare, Medicare/Medicaid, or Medicaid facilities.

The SA reports complaints with deficiencies cited to the RO or SMA, as appropriate, using the following criteria:

a. Immediate and Serious Threat To Patient Health and Safety.

(1) Documentation To Be Forwarded.--Forms HCFA-562, HCFA 670, HCFA-2567, and any appropriate supporting documentation.

(2) Reporting Deadline.--3 working days following the onsite visit.

b. CoP/Condition For Coverage Not Met (No Immediate and Serious Threat To Patient Health and Safety), or Facility Unable or Unwilling To Provide Acceptable PoC For Other Deficiencies.--

(1) Documentation To Be Forwarded.--Forms HCFA-562, HCFA 670, HCFA-2567, and any appropriate supporting documentation.

(2) Reporting Deadline.--55 calendar days following onsite visit.

c. All Conditions Met-Facility Provided Acceptable PoC For Other Deficiencies.--

(1) Documentation To Be Forwarded.--Forms HCFA-562, HCFA 670, and HCFA-2567.

(2) Reporting Deadline.--90 calendar days following onsite visit.

2. SA Special Reporting To RO (Deficiencies Not Cited).--The SA does not normally report to the RO when deficiencies are not cited during an investigation. However, the SA sends the completed Form HCFA-562 and any documentation back to the RO when the complaint originated from the RO.

3. Other Reporting (All Complaints).--In addition to the RO reporting above, the SA closes out all complaints (substantiated and unsubstantiated) with a follow-up notice to the complainant informing him/her of the findings and disposition of the allegation. The SA sends this notice reasonably soon after the investigation and retains a copy with the complaint record.

The SA provides follow-up reports as necessary to any other appropriate parties such as the RO, the SMA, initial referring agencies, or ombudsmen. Be sure to protect the privacy rights of the complainant.

H. Resolution/Closeout.--

1. Deficiencies Not Cited.--After any follow-up notices (see subsection G), the SA enters Forms HCFA-562 and HCFA-670 into the OSCAR Complaint Subsystem and documents the facility's certification file. The SA does not send the package to the RO unless the complaint originated from them.

2. Deficiencies Cited.--The SA enters information from Forms HCFA-562, HCFA-670, and HCFA-2567 into the OSCAR Complaint Subsystem and files its copy of the certification documents in the facility's certification file. The SA sends the complaint package to the RO (titles XVIII and XVIII/XIX) or SMA (title XIX only), as appropriate.

Upon receipt of the SA report, the RO or SMA will process the action as it does any approval with a PoC or adverse action. (See §§3010 and 3012.) The RO or SMA will notify the SA of any additional needed actions, and will provide copies of any appropriate certification or notice documents.

## 3282. SA COMPLAINT MANAGEMENT

General operating requirements for processing certification-related complaints are:

A. Organizational Set-Up.--The SA assigns a separate organizational unit or group of personnel to coordinate and control complaint investigations and follow-up activities. The SA establishes uniform procedures for recording allegations, maintaining data in the OSCAR Complaint Subsystem, and ensuring adherence to all SOM procedures.

B. OSCAR Complaint Subsystem.--The OSCAR Complaint Subsystem is an automated database for monitoring complaint survey activity. Information is entered into the system via the data entry process by the SA and the ROs. The system consists of information derived from Form HCFA-562, Form HCFA-670, Form HCFA-2567, and the Post-Certification Revisit Report (Form HCFA-2567B). The system allows users to add, update, or query complaint records and generate reports. The Complaint Subsystem is used for all facility types, for Medicare, Medicaid, or CLIA facilities. The Complaint Subsystem contains information on both substantiated and unsubstantiated complaint records.

1. Data Entry.--The SA processes all Form HCFA-562s through the Complaint Subsystem. Each complaint record entered into the Complaint Subsystem is directly related to a facility survey and is a result of allegations made against a particular facility. The SA is responsible for data entry of complaint records into the Complaint Subsystem. The SA refers to its OSCAR Data Entry Manual for data entry instructions.

a. Complaints With Deficiencies (Substantiated or Unsubstantiated With Unrelated Deficiencies).--The SA enters Parts I and II of Form HCFA-562 into the OSCAR Complaint Subsystem. The RO completes and enters Part III of Form HCFA-562 for Medicare, Medicare/Medicaid and CLIA facilities. For Medicaid-only facilities, the SA sends Form HCFA-562 to the SMA for completion of Part III. The SMA will then send the form back to the SA for data entry of Part III.

b. Complaints With No Deficiencies (Substantiated With No Deficiencies or Unsubstantiated With No Deficiencies).--The SA enters Parts I and II of Form HCFA-562 into the subsystem, with the exception of Item 15 (Date Forwarded to HCFA RO or SMA). When deficiencies are not cited, the SA does not forward documentation to the RO or SMA, unless the complaint originated with them.

2. Reports.--The OSCAR Complaint Subsystem produces four basic reports that can be used to monitor provider compliance and maintain the SA workload counts. Reports generated by the OSCAR Complaint Subsystem are:

a. Complaint History Profile.--Provides a complaint survey history. This report includes provider identification data and complaint information for the last four complaint surveys in a provider's file. The report highlights basic facts about allegations and investigations and lists deficiencies cited.

b. Summary Complaint File Tabulation.--Represents the aggregate number of complaints added to the complaint file by provider type for the nation, region, or State for a specified time period. A separate listing of provider numbers, names, addresses, and complaint survey dates is available. This report replaces the Quarterly Workload Report.

c. Complaint File Abstract Listing.--Is a synopsis of all complaints in the complaint file. This report includes provider identification and complaint survey data.

d. Complaint Investigations of Facilities With Selected Requirements Out of Compliance.--Lists provider identification data and deficiency data (tag number, literal descriptor, correction date and status) for facilities with a specified requirement or class of requirements (e.g., Conditions, standards, RO flags) out of compliance as a result of the complaint survey.

C. Effects on Survey Schedules.--Complaint investigations should not normally impact upon Medicare/Medicaid certification survey schedules. Complaint visits usually occur between regular, full surveys and focus on a specific problem area only. For CLIA laboratories, see §6105 for information on scheduling surveys. However, if there are potential efficiencies in combining complaint and certification surveys and/or advancing the certification visit date without sacrificing the integrity of either, the SA should do so.

Additionally, the SA considers facilities for more frequent surveys when they present significant compliance problems because of frequent complaints or non-credible PoCs.

D. Provider/Supplier Files.--

1. Complaints With Deficiencies.--The SA places Forms HCFA-562, HCFA-2567, and any other forms or documents related to an individual complaint in the facility's certification file. The SA retains these records, as it does all other certification records. (See §4801.B.)

2. Complaints With No Deficiencies.--The SA keeps any certification documents in the facility's file for a minimum of 1 year. After that, the SA follows in-house file retention policies.

E. Privacy Considerations.--The SA ensures the privacy and anonymity of every complainant. Generally, the SA follows the disclosure procedures under §3308. The SA discloses the complainant's identity only to those individuals with a need to know who are acting in an official capacity to investigate the complaint.

In addition to these Federal requirements, the SA abides by any State procedures not in direct conflict with HCFA instructions. The SA notifies the RO if State regulations conflict directly with any part of these complaint procedures.

F. Program Analysis.--The SA uses the OSCAR Complaint Subsystem discussed in subsection B for evaluation of facility performance and for quality assurance purposes. Data in the subsystem and reports obtained from the subsystem may be used to identify problem facilities and overall performance trends or to analyze the SA complaint processing times, workloads, and training needs.

## 3283. MEDICARE/MEDICAID/CLIA COMPLAINT FORM, FORM HCFA-562

A. Overview.--The SA uses Form HCFA-562 to collect basic, facility-specific information concerning complaints in order to monitor continual compliance of individual Medicare/Medicaid facilities with program requirements, as well as overall SA performance. The SA uses this form only if the allegations reported could result in the citation of a Federal deficiency (i.e., potential violation of Medicare/Medicaid requirements). The SA completes the form for complaints that are investigated by an onsite visit. The SA or the RO are to initiate the form.

Form HCFA-562 will allow multiple complaints against a provider/supplier to be reported at one time. If multiple complaints are received and the allegations are to be investigated at the same time, only one Form HCFA-562 may be completed. The date the first complaint is received in the RO or SA will be the date used for Date Complaint Received (Item 3). Information on the multiple allegations are to be reported on the form using the following fields: Source of Complaint, Total Number of Complainants, Categories of Allegations, and Number of Complainants per Allegation.

Form HCFA-562 is divided into three parts. Part I is completed by the component through which the complaint originated (either RO or SA). Part II is completed by the component actually investigating the complaint (usually the SA). Part III is completed by the component taking the final certification action (RO or SMA). Parts I and II must be completed prior to entry into the OSCAR Complaint Subsystem.

The SA completes Form HCFA-2567 for any investigation that results in the citation of a Federal deficiency. A follow-up Form HCFA-2567B may or may not be included with Form HCFA-562 when forwarded to the RO or SMA. If the follow-up is accomplished after the Form HCFA-562 is completed, the SA does not complete another Form HCFA-562. This would be an update action in the OSCAR Complaint Subsystem to an existing complaint record.

B. Completion Instructions For Medicare/Medicaid/CLIA Complaint Form, Form HCFA-562 (See Exhibit 75).--PART I: To be completed by the SA or the RO. If completed (except Item 7B) by the RO, the form is sent with the complaint allegation to the SA. Item 7B is completed at the time Part II is completed by the investigating office.

CONTROL NUMBER: Enter numeric, alpha, or alpha-numeric number assigned to the complaint by the SA or RO. This is an optional field and, if used, may have from 1 to 12 characters.

Item 1 MEDICARE/MEDICAID/CLIA IDENTIFICATION NUMBER

Enter the 6 or 10-digit identifying provider/supplier number.

Item 2 FACILITY NAME AND ADDRESS

Enter the facility name and address with city/state/zip code.

Item 3 DATE COMPLAINT RECEIVED

Enter the date the complaint allegation(s) is received in the SA or RO. The date must be less than or equal to Item 10. In the case of multiple complaints that are to be investigated during the same site visit, this is the date the first complaint was received.

Item 4 RECEIVING COMPONENT

Enter code for component initiating this form. Acceptable codes are 1 (SA) or 2 (RO).

Item 5 DATE ACKNOWLEDGED

The date the SA or the RO made a telephone call or sent a letter notifying the complainant that the complaint is being investigated. If complaints from multiple sources are investigated during the same survey, this is the date the first acknowledgement is made to a complainant. Date must be in MMDDYY order and greater than or equal to Item 3 (Date Complaint Received).

Item 6A SOURCE OF COMPLAINT

Enter the code that best describes the complaint source (maximum of three sources may be completed). Codes 1 through 5 are acceptable.

Item 6B TOTAL NUMBER OF COMPLAINANTS

Enter the total number of people reporting complaints for a particular facility. Numbers 1 through 99 are acceptable.

Item 7 ALLEGATIONS

One form may accommodate multiple allegations made by a complainant(s). From one to five different categories of allegations may be entered on the form. If more than five allegations are investigated during one survey visit, ensure that all substantiated allegations are recorded on Form HCFA-562. For each allegation you must complete 7A (Category), 7B (Findings), and 7C (Number of Complainants per Allegation).

Item 7A CATEGORY

For each different allegation (Numbers 1 through 5) enter the category code most descriptive of the problem. A maximum of five allegations of different categories may be entered. If different allegations of the same category are investigated simultaneously, they should be combined on the same line. Acceptable category codes are 1 through 9. Category 4 (Patient Dumping) is only valid for hospital providers.

Item 7B FINDINGS

Following the investigation, indicate the finding code appropriate to each allegation reported:

1 = SUBSTANTIATED - One or more allegations were verified and deficiencies were cited that were related to the allegations being investigated or one or more allegations occurred and were verified but the allegations were corrected prior to the complaint investigation and no deficiencies were written.

2 = UNSUBSTANTIATED - None of the allegations were verified but deficiencies were observed and cited in other areas that were not related to the original allegations being investigated or none of the allegations were verified and no deficiencies were cited.

Item 7C NUMBER OF COMPLAINANTS PER ALLEGATION

Enter the total number of complainants for each different allegation reported. Numbers 1 through 99 are acceptable. The number of complainants entered for each allegation cannot be greater than the number reported in Item 6B. For each Number of Complainants there must be a corresponding entry in 7A and 7B.

Item 8 ACTION

Enter one action code describing the first action taken for any or all allegations. (Only one code can apply). Acceptable codes are 1 through 7.

PART II: To be completed by the office that performed the investigation.

Item 9 INVESTIGATED BY

Enter appropriate code for the investigating agency. Acceptable codes are 1 through 3.

Item 10 COMPLAINT SURVEY DATE

Enter the date the first on-site visit was completed in response to the allegation(s). This is the date the investigation was actually completed; that is, the last day the surveyors were physically at the facility for the initial complaint visit. For example: If the investigation is completed in one day, that is the date of survey. If the investigation is done over a two day period, the date of survey is the second day. If the survey is done two consecutive days one week and one day the next week, the date of survey is the day the surveyors were at the facility during the second week.

Item 11 FINDINGS

This item remains blank. At the completion of the investigation, findings for each allegation should be recorded in Item 7B.

Item 12 ACTIONS PROPOSED/TAKEN BY SA OR RO

Enter the proposed actions taken by SA or RO as a result of the investigation findings (maximum of three proposed actions may be completed). Acceptable codes are 1 through 22.

Item 13 DATE OF PROPOSED ACTION

Enter the date of sign-off of the earliest proposed action taken by the SA or RO. The date must be greater than or equal to Item 10.

Item 14 PARTIES NOTIFIED AND DATES

Following the complaint survey, the SA or RO sends out a letter informing the appropriate parties of the findings and disposition of the allegations. Key the code and date for each party notified. Acceptable codes are 1 through 4. A maximum of three parties may be entered. The party notified cannot be coded "2" (Complainant) if Item 6A (Source of Complaint) is coded "4" (Anonymous). Each party must have a corresponding notification date. Date must be greater than or equal to Item 13 (Date of Proposed Action). The date Form HCFA-2567 is mailed to the facility can be considered as the date the facility was notified for complaints with deficiencies cited.

Item 15 DATE FORWARDED TO HCFA RO OR SMA

Enter the date that Form HCFA-562 is forwarded to the RO (title XVIII, XVIII/XIX) or SMA (title XIX only). The date must be greater than or equal to Item 13. Form HCFA-2567 must be attached to Form HCFA-562 if deficiencies are cited. Item 15 does not need to be completed if no deficiencies were cited and the complaint originated from the SA. If Item 4 is coded "2" then Item 15 must be completed. Form HCFA-2567B may be included if a follow-up visit was accomplished prior to forwarding Form HCFA-562 to the RO or SMA.

PART III: Only completed by RO (title XVIII, XVIII/XIX) or SMA (title XIX only) if deficiencies are cited. When Part III is used, it must have Items 16, 17, and 18 completed. For a complaint with no deficiencies cited, Part III is only completed if the complaint originated from the RO or SMA.

Item 16 DATE OF HCFA RO/SMA RECEIPT

Enter the date that Form HCFA-562 is received in the RO (title XVIII, XVIII/XIX) or SMA (title XIX only). The date must be greater than or equal to Item 15.

Item 17 HCFA RO/SMA ACTION

Enter the code of the final action by the RO or SMA. (Only one action may apply). Acceptable codes are 1 through 13.

Item 18 DATE OF FINAL ACTION SIGN-OFF

The date that the RO/SMA action was signed. The date must be greater than or equal to Item 16 (Date of HCFA RO/SMA Receipt).

## 3284. RO PROCESSING GENERAL, CERTIFICATION-RELATED COMPLAINTS

The extent and nature of RO involvement with a given complaint varies depending on the nature of the allegation and the receiving organization. The following procedures address the major variants of RO involvement.

A. Pre-Investigation Actions on Allegations Originating Through the RO.--Most complaints originate through the SA and are recorded and controlled by them. When a complaint is filed directly with the RO, however, the RO assumes those initial SA responsibilities.

The RO establishes procedures and clear organizational accountability to ensure that any complaint originating through the RO is properly evaluated, documented, acknowledged, and handled timely and appropriately.

B. RO Processing of SA Investigated Complaints.--Most complaints are investigated by the SA, no matter where the allegation originated. The RO only becomes actively involved if and when a certification action is needed or in the situations set forth in 3281.D.

Typically, the RO gets involved after an SA investigation:

1. SA Reporting.--

a. Complaints With Deficiencies Cited, Medicare, Medicare/Medicaid/CLIA Complaints.--Following investigation, the SA reports on each Medicare or Medicare/Medicaid/CLIA certification-related complaint with deficiencies cited. It is the SA's responsibility to enter Parts I and II of Form HCFA-562, Form HCFA-670, and Form HCFA-2567 into the OSCAR Complaint Subsystem. The SA then sends the complaint package to the RO. The complaint package, at a minimum, must include Form HCFA-562 (see Exhibit 75), Form HCFA-670, and Form HCFA-2567.

The SAs report as follows:

o Immediate and Serious Threat To Patient Health and Safety.--

- Documentation To Be Forwarded by SA.--Form HCFA-562, Form HCFA-670, Form HCFA-2567, and other appropriate supporting documentation.

- Reporting Deadline.--The deadline for reporting is 3 working days following the onsite visit.

o Condition of Participation/Coverage Not Met (No Immediate and Serious Threat To Patient Health and Safety), or Facility Unable or Unwilling to Provide Acceptable PoC For Other Deficiencies.--

- Documentation To Be Forwarded By SA.--Form HCFA-562, Form HCFA-670, Form HCFA-2567, and other appropriate supporting documentation.

- Reporting Deadline.--The deadline for reporting is 55 calendar days following onsite visit.

o All Conditions Met; Facility Provided Acceptable PoC For Other Deficiencies.--

- Documentation To Be Forwarded By SA.--Form HCFA-562, Form HCFA-670, Form HCFA-2567, and other appropriate supporting documentation.

- Reporting Deadline.--The deadline for reporting is 90 calendar days following onsite visit.

The documentation discussed above is generally all the documentation that the RO receives from the SA. The RO may, however, request additional documentation for allegations the RO originally referred to them.

b. Complaints With No Deficiencies Cited.--The SA does not normally report to the RO on complaints with no deficiencies cited. It is the SA's responsibility to enter Items 1-14 of Form HCFA-562 into the OSCAR Complaint Subsystem. Part III of Form HCFA-562 is not completed for complaints without deficiencies. The SA does not forward the complaint package to the RO unless the complaint originated with the RO. In this case, the SA completes Item 15. The RO completes Part III of Form HCFA-562 when the complaint package is received.

2. RO Actions.--The RO acts on SA investigated complaints and certification documents as follows: (Also see Chapter 7 for SNF/NFs)

a. Certification Actions (Complaints With Deficiencies Only).--The SA forwards certification documentation to the RO for any complaint with deficiencies cited. The RO processes as follows:

o Immediate and Serious Threat To Patient Health and Safety.--The RO processes under expedited termination procedures at §3010. The RO completes and enters Part III of Form HCFA-562 into the OSCAR Complaint Subsystem, following regular data entry and record-keeping procedures.

o Condition of Participation/Coverage Not Met (No Immediate and Serious Threat).--The RO processes as a termination under §3012 for all providers. The RO completes and enters Part III of Form HCFA-562 into the OSCAR Complaint Subsystem, following regular data entry and recordkeeping procedures.

o All Conditions Met - Facility Unable or Unwilling To Provide Acceptable PoC For Other Deficiencies.--If the SA is not able to obtain an acceptable PoC, it will send the RO the appropriate documents to process a termination. Terminate per procedures at §3012. The RO completes and enters Part III of Form HCFA-562 into the OSCAR Complaint Subsystem, following regular termination data entry and record-keeping procedures. The RO notifies the facility that only correction of the deficiencies will avoid termination.

A facility has a right to refuse to submit a PoC if it believes it has enough evidence to show that a deficiency is invalid. The RO examines the documentation presented by a facility that a deficiency did not exist and reconsiders the deficiency determination. If necessary, the RO has the documentation reviewed by an individual who was not involved in making the original determination. Disputes are usually resolved at the SA; however, in the event that the RO does a complaint survey or the SA is unable to resolve a problem, a facility may present the documentation to the RO. If a deficiency did not exist, the RO removes the citation from Form HCFA-2567. If it is determined that the evidence indicates a deficiency, the RO explains the rationale to the facility and request the submission of a PoC.

o All Conditions Met - Facility Provides Acceptable PoC For Other Deficiencies.--the RO reviews and approves (if appropriate) the PoC. The RO completes and enters Part III of Form HCFA-562 into the OSCAR Complaint Subsystem. The RO files Form HCFA-562 and Form HCFA-2567 in the facility certification file.

b. Complaint Records (Complaints With Deficiencies).--In addition to processing the certification actions for any complaint with deficiencies cited, the RO completes Part III of Form HCFA-562. The RO enters Part III of Form HCFA-562 into the OSCAR Complaint Subsystem and retain all hardcopy documents in the facility certification file.

c. Special Processing.--In addition to the more routine reports, the RO may receive:

o RO Referrals.--These consist of SA investigation reports, certification forms, etc. for allegations that originated with the RO and were subsequently referred to the SA for investigation.

In these instances, the RO closes out the established controls. If the complaint has:

- Deficiencies Cited.--Follow the same RO processing procedures the RO would use for SA complaints with deficiencies cited. (See §1131.2.B.1 and 2.)

- No Deficiencies Cited.--Closeout the action and file documents in facility certification file. Complete and enter Part III of Form HCFA-562 into the OSCAR Complaint Subsystem.

o Special Alerts.--In addition to SA reports following investigation, the SA may provide the RO with early alerts concerning complaints having special significance, sensitivity, or media involvement.

C. RO Processing of RO Investigated Complaints.--This less frequent class of complaints includes allegations retained by the RO (see §3281.D) or forwarded to the RO by the SA for investigation or special processing. RO responsibilities vary based on the type of complaint. (Also see Part 7 of the SOM for SNFs/NFs.)

1. Direct RO Investigation.--These procedures apply when direct RO investigation is called for; i.e., Federal facilities, Christian Science sanitoria, or special situations where the RO opts to investigate directly. When directly investigating, the RO begins by ensuring that all initial data collection and acknowledgement requirements in §3281 have been met by either the RO or the SA.

If the allegation involves an immediate and serious threat to patient health and safety, the RO investigates within 2 working days. Otherwise, the RO schedules the investigation based on the severity of the allegation(s).

2. Conducting the Investigation.--The RO follows the procedures for investigation in §3280.

3. RO Documentation.--Following the investigation, the RO documents as follows:

a. Allegations With No Deficiencies.--Completes Items 1-14 of Form HCFA-562. Notifies the complainant and any other parties, enters the complaint record in the OSCAR Complaint Subsystem, closes out any controls, and retains any complaint records in the facility's certification file. The RO does not perform steps 4 and 6.

b. Allegations With Deficiencies.--Provides a statement of deficiencies to the facility and obtain a PoC following routine certification procedures. Documents as follows:

o For Immediate and Serious Threat To Patient Health and Safety.--Completes Form HCFA-562, Form HCFA-2567, and any other appropriate supporting documents.

o For Condition of Participation/Coverage Not Met (No Immediate and Serious Threat To Patient Health and Safety), or Facility Unable or Unwilling to Provide Acceptable PoC For Other Deficiencies.--Completes Form HCFA-562, Form HCFA-2567, and any appropriate supporting documents.

o For All Conditions Met - Facility Provided Acceptable PoC For Other Deficiencies.--Completes Form HCFA-562 and Form HCFA-2567.

4. RO Action (Complaints With Deficiencies Only).--The RO processes the preceding certification documents as follows:

a. Immediate and Serious Threat To Patient Health and Safety.--Processes under expedited termination procedures at §3010. Follows regular data entry and record-keeping procedures.

b. Condition of Participation/Coverage Not Met (No Immediate and Serious Threat).--Processes as a termination under §3012. Follows regular data entry and record-keeping procedures.

c. All Conditions Met - Facility Unable or Unwilling To Provide Acceptable PoC For Other Deficiencies.--If the SA was not able to obtain an acceptable PoC, it will send the RO the appropriate documents to process a termination. The RO terminates per procedures at §3012, and follows regular termination data entry and record-keeping procedures.

d. All Conditions Met - Facility Provides Acceptable PoC For Other Deficiencies.--Reviews and approves (if appropriate) the PoC. Files Form HCFA-562 and Form HCFA-2567 in facility certification file.

5. Notice.--Notifies the complainant in writing concerning any findings.

6. Complaint Closeout (Complaints With Deficiencies Only).--Ensure that Form HCFA-562 and Form HCFA-2567 are entered into the OSCAR Complaint Subsystem, closeout the action, forward a copy to the SA and the SMA (if appropriate), and retain all hardcopy documents in the facility certification file.

D. Special RO Processing.--The following types of allegations are subject to special RO handling:

1. Accredited Hospitals.--The RO follows procedures at §3260-3274. The RO completes a Form HCFA-562;

2. CLIA Laboratories;

3. Blood Transfusion-Related Fatalities;

4. Over-Utilization or Inappropriate Utilization of Services.--The RO refers to local PRO for investigation and record allegation and findings on Form HCFA-562 and documents facility files as for other allegations. The RO acts, as necessary, on any findings returned by the PRO;

5. Civil Rights Violations.--The RO refers to the regional OCR for investigation. The RO records allegations and findings on Form HCFA-562 and document facility files as for other allegations. The RO acts as necessary on any findings returned by OCR; and

6. Medicare/Medicaid/CLIA Fraud.--The RO refers to the RO of the Inspector General/DHHS for investigation. The RO records allegations and findings on Form HCFA-562 and document facility files as for other allegations.

In each of the above instances, the RO ensures that the complainant and SA are notified of any findings.

E. RO Completion Instructions For Form HCFA-562.--Part I: To be completed by the SA or RO. If the RO completes (except Item 7B) the form, it sends it with the complaint allegation to the SA. Item 7B is to be completed at the time Part II is completed by the investigating office. )See §3283.)

Part III: Completed by RO (title XVIII, XVIII/XIX) or SMA (title XIX only) if the complaint has deficiencies cited. If Part III is used, Items 16, 17 and 18 must be completed. Part III is completed for complaints with no deficiencies cited only if the complaint originated from the RO and was sent to the SA for investigation.

Item 16 DATE OF HCFA RO/SMA RECEIPT

Enter the date that Form HCFA-562 is received in the RO (title XVIII, XVIII/XIX) or SMA (title XIX only). The date must be greater than or equal to Item 15.

Item 17 HCFA RO/SMA ACTION

Enter the code of the final action by RO or SMA. (Only one action may apply.) Acceptable codes are 1 through 6.

Item 18 DATE OF FINAL ACTION SIGN-OFF

The date that the RO/SMA action was signed. The date must be greater than or equal to Item 16 (Date of RO/SMA Receipt).

## 3285. RO COMPLAINT MANAGEMENT

General operating requirements for an RO program for processing general, certification-related complaints are discussed below.

A. Organizational Set-Up.--The RO establishes clear accountability for coordination and control of complaints. The RO disseminates uniform procedures for recording allegations, referring them to the SA, ensuring adherence to procedures, and maintaining processing control systems.

B. Processing Control System.--The RO establishes a complaint processing control system (either manual or automated) to ensure timely and appropriate action on all allegations originating with or investigated by the RO. The system should track allegations through closeout.

C. Recordkeeping.--

1. General.--The RO maintains a master complaint log or optional computer system summarizing information from all Form HCFA-562s (RO or SA investigated), and similar information for any other RO investigated complaints. This system is intended to give the RO rapid access to information on:

- o All significant, substantiated complaints in the region; and
- o All RO investigated complaints of any kind.

This system could be combined with the processing control system, but the records should be kept distinct since they serve two different purposes.

2. Provider/Supplier Files.--

a. Substantiated.--The RO retains Forms HCFA-562 (if applicable), HCFA-462, HCFA-2567, and HCFA-1539, and any other forms or documents related to an individual complaint

in the facility certification file. The RO retains these records for the current and most recent certification period.

b. Unsubstantiated.--The RO retains any documents for an unsubstantiated allegation in the facility file for a minimum of 1 year.

D. Privacy Considerations.--The RO protects the privacy and anonymity of the complainant, and discloses the complainant's identity only to those individuals with a need and right to know who are acting in an official capacity.

In addition to these Federal requirements, the RO accommodatea applicable State procedures not in direct conflict with HCFA privacy procedures or program requirements.

E. Certification Procedures.--If the facility file is being examined at the time of recertification, the RO reviews complaint documentation in file. This historical data is a good indication of the facility's performance. The facility's PoCs are good indicators of its responsiveness to correction requests.

F. Title XIX Oversight.--The RO considers any complaint data regarding Medicaid-only facilities in targeting look behind surveys or reviews.

G. Program Analysis.--The RO will have specific data from all Form HCFA-562s in summary form - either through a log or data system. (See subsection C.1. and §3282.B.2)

These records should include:

- o Identification of region or State-wide patterns;
- o Pinpointing of problem facilities or States;
- o Evaluation of SA processing times, workloads, performance, etc.; and
- o Identification of overall SA workloads, including unsubstantiated and Medicaid-only complaint volumes.

H. Training and Technical Assistance.--The RO includes training and information needs identified above, as a basis for SA training, and technical assistance activities.

## 3298. COMPLAINTS INVOLVING HIV-INFECTED INDIVIDUALS

As direct recipients of Federal funds, providers and suppliers are subject to provisions of §504 of the Federal Rehabilitation Act of 1973. Symptomatic and asymptomatic individuals who are infected with the human immunodeficiency virus (HIV) or "AIDS virus" are protected by the Rehabilitation Act as "individuals with handicaps." Therefore, HIV-infected individuals who are provided services, are employed, or are to be employed by providers and suppliers in Federally-conducted or financed programs or activities would be treated like anyone else in the workforce, so long as these individuals do not (on a case-by-case basis) pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

A facility participating in the Medicare or Medicaid programs cannot discriminate against individuals who are HIV-infected so long as these individuals do not (on a case-by-case basis) pose a substantial health and safety risk to others and so long as the facility provides comparable services and care to non HIV-infected individuals.

The SA or the RO refers discrimination complaints to OCR, which is the authority to determine whether Medicare or Medicaid providers and suppliers comply with this non-discrimination statute.

Handling Public Inquiries

## 3300. CONFIDENTIALITY AND DISCLOSURE OF RECORDS - CITATIONS AND APPLICABILITY

Section 1106 of the Act prohibits disclosure of any file, record, report, or other writing, or any information obtained at any time by or from the Secretary or an office or employee of DHHS in the course of discharging his duties under the Act, except as prescribed by regulations. The applicable regulations are found in 42 CFR 401, Subpart B (Confidentiality and Disclosure).

The regulations set out what records are available, how they may be obtained, and, where applicable, when a fee is paid to offset the cost of administrative activity involved in furnishing the information.

## 3302. FEDERAL FREEDOM OF INFORMATION ACT (FOIA)

Coexisting with the confidentiality provision of §1106 of the Act are the provisions of the 1967 "Freedom of Information" amendment to the Administrative Procedures Act. This amendment establishes the right of the public to access numerous types of Federal records and information. Exempted from mandatory disclosure under this amendment, however, are records and information which other Federal confidentiality statutes prohibit being disclosed. See 42 CFR 405.118 regarding the deletion of identifying details.

## 3304. MULTI-PROGRAM INFORMATION IN SA FILES

HCFA's rules governing disclosure of Medicare/Medicaid/CLIA records and information to the public may be more or less restrictive than SA rules or those of other Federal programs. The SA should carefully distinguish between:

A. Records and information the SA acquires as an agent of a HCFA program, and

B. Other records and information which:

1. The SA independently acquires through a State program; or

2. Are known to other parties who are not subject to a restriction or disclosure. The information known to these parties is considered as having entered the public domain.

Only the information the SA acquired in its role as an agent of HCFA, and which has not otherwise entered the public domain, is subject to HCFA's disclosure rules.

When the SA obtains a record or an item of information that is not in the public domain and is held for joint use by the Medicare/Medicaid programs and other State or Federal programs, the SA applies the most restrictive confidentiality policies of all the programs to which the information relates.

Once any record or item of information has been forwarded to HCFA, it is treated according to whatever HCFA rule is applicable. Consequently, the SA is free to disclose the information listed in §3308 below, either on the basis that the State is an agent of the Medicare/Medicaid/CLIA program or on the basis that such information has entered the public domain through HCFA.

## 3308. INFORMATION WHICH MAY BE DISCLOSED TO PUBLIC

A. Information Disclosable To Public Under HCFA Rules That May Be Disclosed Directly By the SA.--

1. A facility does or does not participate in the Medicare/Medicaid/CLIA program;

2. The official Medicare/Medicaid/CLIA report of a survey, except to the extent that it contains:

- o The name of any patient;
- o Medical information about any identifiable patient;
- o The identity of a complainant;
- o The address of anyone other than an owner of the facility; or
- o Information which could be defamatory toward any identifiable person.

NOTE: The SA reviews the report of survey, and if it contains any of the above elements, it deletes the information from the report by blocking it out fully prior to release of the report. (See 42 CFR 401.118);

3. Citations of deficiencies which have been conveyed to the provider following a survey, except to the extent the report contains any of the identifiable information listed above. The SA blocks this information out prior to release of the statement of deficiencies;

4. PoC and pertinent comments submitted by the provider relating to Medicare/Medicaid/CLIA deficiencies cited following a survey, except to the extent the PoC or comments contain any of the identifiable information listed above. The SA blocks this information out prior to release of the PoC;

5. Official notices of involuntary provider termination;

6. Reports and information about a laboratory's performance in proficiency testing programs;

7. HCFA manuals distributed to the SAs, intermediaries, carriers, providers, or suppliers; and

8. Statistical data on provider characteristics which do not identify any specific provider or individual.

## 3310. REQUESTS FOR INFORMATION ABOUT NON-PARTICIPATING INSTITUTIONS

Information disclosable about an institution, agency, organization, or supplier which has never been surveyed for participation in the Medicare/Medicaid/CLIA program is limited to the fact that it has never participated.

## 3312. CHARGES FOR INFORMATION

If a member of the public requests from HCFA copies of the records and information described in §3308 of this manual, there will generally be a charge. The SA does not provide free copies of more than a few pages of disclosable information if the cost of reproduction is to be charged to the Medicare/Medicaid/CLIA program. Charges should be in accordance with 42 CFR s 401.136 and 401.140 for Medicare, or with any applicable State fee schedules for reproduction.

## 3314. TIME PERIODS FOR DISCLOSURE

For Medicare, §1864(a) of the Act specifies that the Secretary shall disclose survey information within 90 days following the completion of each survey. Implementing regulations in 42 CFR 401.133(a) and (b) further provide that survey-related information prepared by the State and responded to by the facility must be disclosed within 90 days following completion of the survey by the State but may not exceed 30 days following HCFA's receipt of such information, or if prepared by HCFA, within 30 days following the final preparation.

For Medicaid, §1902(a)(36) of the Act and 42 CFR 431.115 provide that survey-related information must be disclosed either upon determining that a provider is eligible to be certified or recertified, or within 90 days after completion of the survey, whichever occurs first. Any applicable State law(s) would also be considered.

Sections 1819(g)(5) and 1919(g)(5) of the Act provide disclosure requirements specific to SNFs and NFs within 14 calendar days after the information is made available to the facility. (Also see 42 CFR 488.325.)

For both Medicare and Medicaid, the date the survey is completed is the last day of the survey.

The provisions of FOIA require that when a request to disclose information is received, the information be released within 10 working days, or if this is not possible, the requestor be notified within 10 working days when the information will be released. Follow this policy unless the State has other disclosure rules in which case those rules apply to the time allowed for disclosure. (See 42 CFR 401.136.)

When the SA receives a request for information, disclosure of which is not clearly permissible under the preceding sections, the SA declines to disclose the information requested on the basis of the provisions of §1106 of the Act and refers the request to the RO. The SA notifies the requestor of this action within 10 working days and directs the requestor to contact the RO for additional information concerning the denial. (See 42 CFR 401.126.)

## 3316. INFORMATION FURNISHED TO ORIGINAL SOURCE

Any party is entitled to information which that party supplied initially. Accordingly, one copy of the current survey report (subject to the restrictions in §§3308 and 3320) or other official form completed by or for the provider/supplier, correspondence from the provider/supplier, and documentation submitted by the provider/supplier may be furnished to the original source without charge.

When a request is made by a provider/supplier to examine or secure copies of documents it has submitted, but the item requested has been sent to the RO, the SA acknowledges receipt of the request and refer the request to the RO, which will arrange for the original documents to be examined or copied, as appropriate.

## 3318. DISCLOSURE OF INFORMATION TO AND FROM OPERATING COMPONENTS

The SA may disclose confidential certification information about a provider/supplier without the provider/supplier's authorization when such disclosure is necessary for proper performance of the duties of:

- An officer or employee of DHHS;
- An officer or employee of a SA or an intermediary participating in administration of title XVIII and/or title XIX by contract, agreement, or State plan for purposes of carrying out such contract, agreement, or State plan; and
- An officer or employee of a SA carrying out duties under State law in licensing or approving facilities.

Generally, confidential certification information is not to be released outside of the State survey and certification unit. Release by a SA to another State component or to a county or other local entity which performs survey functions for the SA is predicated on first obtaining agreement by the component or county to use the information only for certification or licensure purposes. The receiving SA component or other State or local entity may not release any certification information, subject to the penalty provisions of §1106 of the Act.

## 3320. NECESSARY PRECLEARANCE WITH RO BEFORE RELEASING CONFIDENTIAL INFORMATION

The SA obtains advice from the RO when a request is received for confidential Medicare and/or Medicaid information under circumstances other than as permitted by §3308. To the extent known, indicate the purpose to be served by the release, the specific information to be released, and, if appropriate, the availability of the information elsewhere.

Additional State Agency Responsibilities

## 3330. HHA TOLL-FREE HOTLINE AND INVESTIGATIVE UNIT

Section 1864(a) of the Act requires that the State establish a toll-free hotline to collect, maintain, and continually update information on Medicare participating HHAs including certification-related deficiencies found regarding patient care, corrective actions, and sanction activity during its most recent survey. Complaints and questions will also be received over the hotline concerning HHAs in the State. The State is to inform Medicare beneficiaries of the availability of the hotline, its purpose, the hotline telephone number, and hours during which it is in service. The SA (under the §1864 agreement) may subcontract with the appropriate State or local agency for operation of the toll-free hotline. However, the SA is required to investigate certification-related complaints received by the hotline.

The instructions are minimum requirements for establishing and maintaining the hotline. Additional operating procedures may be used to complement the requirements. This activity will be monitored by the RO and enforced through the §1864 agreement process.

A. HHA Hotline Function.--

- Operate the toll-free hotline 6 hours per day (between 7:00 a.m.-6:00 p.m.) Monday - Friday, except on State or Federal holidays. Notify the public in advance if there are changes in hours of operation;
- Provide HHA hotline information to HHAs and the public by telephone or in writing;
- Record most recent certification and enforcement findings regarding patient care within 30 days of the determination of certification or recertification, approved PoC, correction of deficiencies, and any sanctions imposed, including termination of a Medicare participating HHA;
- Record complaints received on the HHA hotline;
- Refer HHA hotline certification-related complaints to the survey unit for possible investigation; and
- Refer non-certification related complaints to the appropriate components in the State agencies.

B. HHA Hotline Information.--These items must be maintained and readily retrievable:

- Name, address, and Medicare provider number of Medicare HHAs in the State;
- Date of most recent Medicare certification or recertification survey of individual HHAs;
- Record of any Condition level deficiencies found regarding patient care in the most recent survey conducted by the SA;
- Date(s) of planned corrective action(s) and completed corrective action(s) for Condition level deficiencies; and
- Date(s) and type of sanction(s), if any imposed, including termination.

C. Disclosure of Information.--When responding to calls requesting information, the SA releases the information verbally and as necessary in writing in accordance with HCFA public disclosure rules. (See §§3300-3320.)

D. Recordkeeping Requirements.--The SA records each call as either a complaint or a general inquiry. The recordkeeping system may be manual or automated and must indicate the general nature of the inquiry or complaint and the resolution, i.e., question answered, material sent, or complaint referred for investigation.

E. Public Awareness.--The State is to notify Medicare beneficiaries and HHAs in its State of the availability of the hotline. In addition, the State is to notify each Medicare HHA in the State about the HHA hotline, the telephone number, purpose, and hours of operation.

F. Hotline Investigative Unit.--The SA investigates the certification-related complaints received by the hotline following procedures in §§3280-3282. In instances where a complaint is not certification-related, the SA refers that complaint to the proper State agency (e.g., the State medical society, the State licensure agency, or the State social services department), or the RO.

## Response To Subpoenas Served On and Suits Against the State Agency

### 3350. SUBPOENA FOR PROGRAM RECORDS

When one of the officers or employees of a SA is served with a subpoena or other legal proceeding to produce title XVIII and/or title XIX records or CLIA record, whether or not the information is partly or wholly disclosable, accept the subpoena. The SA should immediately notify its legal advisor or counsel and the RO of receipt of the subpoena, and provide copies of the subpoena and other pertinent documents to both. The SA determines whether the subpoenaed records and information are routinely disclosable to the public or contain confidential information which is normally withheld. The SA includes this information with the notification.

The SA should place the subpoenaed records and information in a secure area to prevent unauthorized disclosure and assure the availability to counsel for review.

If not included in the subpoena but known to the SA, it informs its legal advisor and the RO of the names, addresses, and telephone numbers of the presiding judge and attorneys, and the purpose of the subpoena.

After the RO receives the materials, it coordinates with the the SA legal advisor and takes other actions necessary to assist the SA. After consultation with the SA, the RO and the SA legal advisor determine whether the SA must produce the subpoenaed records and information and if so, notify the SA director to comply. If it is determined that all or part of the subpoenaed records and information are to be withheld, the RO and/or SA legal advisor represents the SA in dealing with the court of jurisdiction and enter the motions to quash the subpoena, based on the provisions of §1106 of the Act which prohibits disclosure of confidential records and information and other pertinent statutes and regulations.

### 3352. FORTHWITH SUBPOENA

On rare occasions the SA may be served with a Forthwith Subpoena. Unlike a standard subpoena which requires that records and information be produced on a specified date and delivered to the court, a Forthwith Subpoena requires that the SA immediately provide the subpoenaed records and information. The SA accepts the subpoena and requests the individual to wait.

The SA immediately notifies its SA legal advisor and requests that the legal advisor call the RO.

The RO and the SA legal advisor will determine by telephone the appropriate action to be taken. The SA legal advisor will deal with the individual waiting for the records and information. The SA should not take unilateral action of any type.

### 3354. SUBPOENA FOR SA LICENSURE RECORDS

If the SA has integrated certification and licensure files and it receives a subpoena requiring it to produce licensure information, it should consult with the RO before complying with the subpoena to determine if the integrated file contains information prohibited from disclosure by §1106 of the Act. (See §3300.) If the files contain such information, the RO assists the SA legal advisor in determining the appropriate procedures and action to be taken in responding to the subpoena.

## 3356 SUIT AGAINST SA

Where a suit is brought against the SA as a result of its title XVIII and/or title XIX or CLIA functions, the SA forwards the notice of the suit to the RO. The RO coordinates with the SA and its legal advisor.

## Conducting Investigations for Alleged Violations of 42 CFR 489.24 and/or the Related Requirements at 42 CFR 489.20(l), (m), (q), and (r): Responsibilities of Medicare Participating Hospitals in Emergency Cases

### 3400. BACKGROUND

Section 1866 of the Social Security Act (the Act), Agreements with Providers of Services, specifies that for a hospital (or any provider of services) to qualify for participation in the Medicare program, it must enter into an agreement with the Secretary of HHS. Effective August 1, 1986, participating hospitals with emergency departments must comply with the requirements of §1867 of the Act as a condition of their provider agreement.

The following Medicare provider agreement requirements, which closely parallel provisions contained in §1866 of the Act, must be met by Medicare participating hospitals with emergency departments:

- 42 CFR 489.20(l) requires a hospital to comply with the requirements of 42 CFR 489.24. (Section 1866(a)(1)(I)(I) of the Act requires a hospital to have and enforce policies to ensure compliance with the requirements of §1867.)

- 42 CFR 489.20(m) requires a hospital to report to HCFA or the State survey agency any time it believes it has received an individual who has been transferred from another hospital in violation of 42 CFR 489.24.

- 42 CFR 489.20(q) requires a hospital to post conspicuously a sign(s) specifying the rights of individuals, under §1867 of the Act, with respect to examination and treatment for emergency medical conditions and women in labor and to indicate whether or not the hospital participates in the Medicaid program.

- 42 CFR 489.20(r)(1) requires a hospital to maintain medical and other records related to individuals transferred (including discharged) to or from the hospital for a period of five years from the date of transfer.

- 42 CFR 489.20(r)(2) requires a hospital to maintain a list of physicians who are on call to provide treatment necessary to stabilize an individual with an emergency medical condition.

- 42 CFR 489.20(r)(3) requires a hospital to maintain a central log on each individual who comes seeking assistance and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, stabilized and transferred, or discharged.

When hospitals do not conform to the requirements of §1867, the practice is commonly called "dumping." A hospital with an emergency department is defined in 42 CFR 489.24(b) as a hospital that offers services for emergency medical conditions within its capacity to do so. The regulations at 42 CFR 489.24 parallel the provisions of §1867 of the Act and place the following requirements on a hospital that has an emergency department:

- 42 CFR 489.24(a) requires the hospital to screen all individuals who come to the hospital and request an examination or treatment for an emergency medical condition.

- 42 CFR 489.24(c) requires a hospital to provide either further medical examination and such treatment as may be required to stabilize the medical condition within the staff and facilities available at the hospital, when the hospital determines that the individual has an emergency medical condition, or to transfer the individual in accordance with the requirements of 42 CFR 489.24(d).

It also identifies the responsibilities of the hospital when an individual refuses consent to further examination, treatment, or transfer, in order to meet the requirements of 42 CFR 489.24.

o 42 CFR 489.24(c)(3) prohibits a hospital from delaying a medical screening examination or stabilizing treatment in order to inquire about an individual's method of payment or insurance status.

o 42 CFR 489.24(d) requires a hospital to appropriately transfer an individual who has an unstabilized emergency medical condition. The hospital may not transfer the individual unless the individual requests the transfer or a physician certifies the medical necessity of the transfer. To make an appropriate transfer, the transferring hospital must provide the medical treatment, within its capacity, which minimizes the risk to the individual, send all pertinent medical records available at the time of transfer to the receiving hospital, effect the transfer through qualified persons and transportation equipment (including life support measures), and obtain the consent of the receiving hospital.

o 42 CFR 489.24(d)(3) provides whistleblower protection to physicians and qualified medical personnel who refuse to authorize the transfer of an individual who has not been stabilized. It also provides whistleblower protections to any hospital employee who reports a violation of 42 CFR 489.24.

o 42 CFR 489.24(e) prohibits a hospital with specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or, in rural areas, regional referral centers) from refusing to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

If a hospital fails to meet these requirements, then HCFA may terminate the provider agreement in accordance with 42 CFR 489.53. The Office of the Inspector General (OIG) has the responsibility and authority to assess civil monetary penalties or to exclude physicians from the Medicare program when a hospital or physician violates these requirements. Additionally, individuals suffering personal harm and medical facilities suffering financial loss as a result of a violation of these provisions can bring civil action under State law against the offending hospital and physicians. Filing for such civil action is limited to a period of two years after the date of the alleged violation. This legislation does not preempt any State or local laws, except to the extent that State or local requirements directly conflict with a requirement of this legislation.

## 3402. BASIS FOR INVESTIGATION

The State survey agency must promptly report to the RO all complaints alleging a violation of the provisions of 42 CFR 489.24 and the related provisions at 42 CFR 489.20(l), (m), (q), and (r). The RO decides whether a complaint alleges a violation of these requirements and warrants an investigation. Refer all complaints to the RO prior to investigation. To expedite investigation, make your referrals by telephone, with written followup via mail, E-mail or FAX.

Complainants are not required to give their names or other identifying information. Either the SA or the RO will make appropriate acknowledgment to the party making the complaint, if known.

## 3404. RO DIRECTION OF INVESTIGATION

A. Evaluation of Allegation.--The RO evaluates all complaints and refers to you those that warrant SA investigation. The SA or the RO also sends a letter to the complainant acknowledging the complaint and informing the complainant of whether an investigation is warranted. Your responsibility is to ascertain, via investigation, whether a violation of 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20 occurred and if there were other violations.

B. Request for Investigation of Allegations.--The RO gives an initial verbal authorization for investigation, then prepares a Form HCFA-1541A, Request for Survey of 42 CFR 489.20 and 489.24, Essentials of Provider Agreements: Responsibilities of Medicare Participating Hospitals in Emergency Cases (Exhibit 136) and forwards it to you with a copy of the allegation(s). The RO also sends you the Form HCFA-562, Medicare/Medicaid/CLIA Complaint Form, along with the Form HCFA-1541A. If the RO identifies conditions or standards it wants you to survey related to the dumping allegation at an accredited hospital, a Form HCFA-2802, Request for Validation of Accreditation Survey is prepared and sent to you in accordance with the procedures in §3262. If the RO identifies conditions or standards it wants you to survey relating to the dumping allegation at a nonaccredited hospital, it will inform you via a memorandum sent along with the Form HCFA-1541A.

## 3406. CONDUCTING AN INVESTIGATION

A. Selecting the Team.--To perform the investigation, select surveyors with a background in the profession or area to be investigated. Preferably, personnel should have acute care training and experience; all surveyors must be adequately trained in the evaluation of 42 CFR 489.24 cases. Physicians should have experience in peer review.

Appropriate physician review may be performed by qualified SA physicians or under agreements or contracts with the State PRO, the State or local medical associations, or other physician groups or individuals. If a SA physician is not available and you think a medical review is needed, indicate on the Form HCFA-1541B, Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report (Exhibit 137), that a physician review is recommended, and sends all of the information to the HCFA RO. The RO will authorize the appropriate PRO or physician consultant to perform the review, if needed. Physician reviewers should be board certified (although it is not required) and be actively practicing in the same specialty or specialties as the physician or physicians who treated the patient whose case resulted in the complaint.

B. Scheduling the Investigation.--Allegations of dumping made against a hospital (non-accredited or accredited) represent a probable immediate and serious threat to the next individual who comes to the hospital requesting examination and treatment for an emergency medical condition. Therefore, complete the investigation within five working days after receipt of the telephone authorization from the RO. DO NOT ANNOUNCE ANY INVESTIGATIONS.

C. Guidelines for Surveyors Conducting Investigations.--

1. Attention to Procedures.--The purpose of conducting the investigation is to ascertain whether or not the hospital violated 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20. The inspection must be in accordance with applicable survey procedures and policies. Review instructions in Appendix V (Interpretive Guidelines and Survey Procedures) before beginning the investigation.

2. Involvement of Complainants.--Complainants, if known, will receive a letter of acknowledgment from the SA or RO. Do not disclose the identity of complainants. When

information obtained during the investigation appears to conflict with the information supplied by the complainant, consult with the complainant if this can be done without disclosing the person's identity.

D. Conducting the Investigation.--To investigate allegations of noncompliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, use the Interpretive Guidelines and Survey Procedures in Appendix V. The guidelines provide a detailed interpretation of the regulations.

A complete investigation consists of assessment of the following components:

- o Completeness, adequacy, and enforcement of policies and procedures which address the provisions of 42 CFR 489.24;
- o Prompt reports to the SA or HCFA of receipt of an improperly transferred individual by the receiving hospital;
- o Presence and completeness of signs posted in emergency departments specifying the rights of individuals under 42 CFR 489.24 and information indicating whether the hospital participates in the Medicaid program;
- o Maintenance of medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of transfer (including discharged patients);
- o Maintenance of a list of physicians who are on call to provide necessary stabilizing treatment;
- o Maintenance of a central log on each individual who comes to the hospital seeking emergency services;
- o Provision of an appropriate medical screening examination sufficient to determine the presence of an emergency medical condition;
- o Provision of necessary stabilizing treatment;
- o Provision of no delay in examination or treatment in order to inquire about insurance status or capability for payment;
- o Provision of an appropriate transfer to another medical facility;
- o Provision of whistleblower protections; and,
- o Adequacy of responsibilities of recipient hospital with specialized capabilities (nondiscrimination).

The survey tasks are listed below for easy reference. See Appendix V for detailed guidance.

- o Task 1 Entrance Conference
- o Task 2 Case Selection Methodology
- o Task 3 Record Review
- o Task 4 Interviews
- o Task 5 Exit Conference
- o Task 6 Professional Medical Review
- o Task 7 Assessment of Compliance and Completion of the Deficiency Report

After the investigation is concluded, complete a Form HCFA-1541B, Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report, (Exhibit 137). If one or more of the provisions at 42 CFR 489.24 or the related requirements of 42 CFR 489.20 are not met, complete a Form HCFA-2567, Statement of Deficiencies and Plan of Correction, using the "Principles of Documentation." Describe in detail the facts of each individual case. In addition, specify whether the hospital was aware of the problem and took steps to remedy it prior to the survey. If a SA physician was a member of the investigation team, include the medical review of the case. Use the Physician Review Outline for Emergency Care Obligations of Medicare Hospitals (Exhibit 138) for this purpose. In addition, complete the Form HCFA-562. All forms must be signed, showing the professional titles of all participating surveyors, and dated.

E. Exit Conference.--It is usually desirable and appropriate to conduct an exit conference. Do not reveal the complainant. You may outline the basic facts uncovered by the onsite investigation. However, you must inform the hospital that the RO will make the final compliance determination, and the determination is often made with information obtained after the onsite investigation. Do not venture an opinion on what determination the RO might make. The exit conference should include a description of the process that is followed if the RO determines that a violation has occurred.

## 3408. FORWARDING REPORT OF INVESTIGATION TO THE RO

Forward the results of the investigation and your recommendations to the RO by the fastest method available within ten working days following completion of the onsite survey if it appears there may be a violation of §1866 or 1867 of the Act. If there appears to be no violation, and conditions of participation are felt to have been met, this timeframe may be extended to 15 days in order to allow the RO additional processing time. Send the following materials to the RO in one package:

- Form HCFA-562, Medicare/Medicaid/CLIA Complaint Form;

- Form HCFA-1541B, Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report. Recommend one or more of the actions below on the form:

1. None.--This means the complaint was not substantiated.

2. In Compliance, But Previously Out of Compliance.--This means that the hospital identified the problem on its own and took effective corrective action prior to the investigation. In addition to this recommendation, document on the Form HCFA-2567 when the violation or a similar problem was identified by the hospital, the corrective action taken, and the date of such action. Also, document that the hospital has had no violations or similar problems for at least the past six months.

3. Recommend Termination (23 day track).--This means that the violation presents an immediate and serious threat to patient health and safety.

4. Recommend Termination (90 day track).--This means that the hospital is out of compliance with 42 CFR 489.24 or the related requirements at 42 CFR 489.20(l), (m), (q) or (r), but the violation does not present an immediate and serious threat to patient health and safety.

5. Request Physician Review.--This means that you recommend that the RO obtain a medical review of the case.

6. Possible Discrimination.--This means that you believe discrimination occurred based on financial status, race, color, nationality, handicap, or diagnosis.

- o Form HCFA-670, Survey Team Composition and Workload Report;
- o Form HCFA-2567, Statement of Deficiencies and Plan of Correction;

NOTE: If the hospital identified the deficiency and took corrective action prior to your investigation, indicate on the HCFA-2567 that the requirement was not met. However, indicate on the HCFA-2567 and the narrative report that the hospital took corrective action prior to the investigation, what action was taken, and for how long the hospital has been in compliance.

- o Physician Review Outline for Emergency Care Obligations of Medicare Hospital (if physician review was done by SA);
- o Complaint investigation narrative;
- o Copies of pertinent hospital policies and procedures that relate to the identified deficiencies;
- o Certification of benefits versus risks of the transfer (if this is a transfer case);
- o Summary listing of all patients comprising the sample (including an explanation of how and why the cases were selected for review);
- o Summary of interviews; and
- o Copies of medical records for substantiated cases, medical records of individuals named in complaints, and any medical records for which a PRO review is requested.

## 3410. RO REVIEW OF INVESTIGATION

The RO reviews the investigation findings. The RO is encouraged to confer with the SA, and may also request medical review of the case by the appropriate PRO or State Agency physician reviewer to determine if there is a dumping violation. With this information, and any other additional information, the RO determines whether the hospital complied with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, and determines whether the violation constitutes an immediate and serious threat to patient health and safety.

Prior to determining compliance or noncompliance, the RO is encouraged to confer with the State Agency, and may confer with the hospital's representatives and share data as possible as limited by current Privacy Act requirements.

A. Hospital Is In Compliance--No Past Violation.--If the RO determines that the allegation is not substantiated and that the hospital is in compliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, the RO notifies the hospital and forwards a copy of the letter to you. If the complaint was received by the SA, you will notify the complainant that the compliant was not substantiated. If the RO received the complaint, the RO will notify the complainant.

B. Hospital Is In Compliance--Past Violation, No Termination.--If the RO determines that the allegation was substantiated, but the hospital identified the violation on its own, took effective corrective action prior to the investigation, and has had no violations of 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20 for at least the past six months, then termination action is not initiated. The RO notifies the hospital via a Past Violation--No Termination Letter and forwards a copy of the letter to you. The RO or SA also sends a copy of the letter to the hospital to the complainant. Although no termination action is taken, the RO must refer past violations of 42 CFR 489.24 to the OIG for assessment of civil monetary penalties (CMPs).

C. Hospital Is Not in Compliance--Immediate and Serious Threat to Patient Health and Safety.--If the RO determines that the hospital is not in compliance and the violation represents an immediate and serious threat to patient health and safety, the RO follows a 23-day termination process. Uncorrected deficiencies that resulted in a violation of 42 CFR 489.24 may pose an immediate and serious threat to people seeking emergency care. The termination procedures in §3412A are followed. The RO will notify the complainant that the complaint was substantiated. It will also inform the hospital in writing of the specific violations via a preliminary determination letter and send the hospital a copy of Form HCFA-2567, Statement of Deficiencies. You will also receive a copy of the letter.

D. Hospital Is Not in Compliance--Situation Does Not Pose an Immediate and Serious Threat to Patient Health and Safety.-- If the RO determines that the hospital is not in compliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20, but the violation does not pose an immediate and serious threat, or the hospital took corrective action after the investigation to remove the immediate and serious threat, the RO follows a 90-day termination process. The termination procedures in §3412B are followed. The RO notifies the complainant that the complaint was substantiated. The RO also informs the hospital in writing of the specific violations via a preliminary determination letter and sends the hospital a copy of Form HCFA-2567, Statement of Deficiencies. You will also receive a copy of the letter.

Examples of noncompliance which usually does not pose an immediate and serious threat include the following scenarios:

1. A transfer which was appropriate, but not signed or dated by the physicians;

2. An appropriate, functioning central log that on one particular day is not fully completed; and

3. A written hospital policy that is missing, but is nonetheless being implemented.

The fact that the hospital has completed a Plan of Correction should not be interpreted to mean that the hospital "admits" violating §1866 or §1867 of the Act. However, the hospital will still be included on the log of facilities with §1867 violations, with the notation that an acceptable plan of correction was received by HCFA, and termination action was stopped.

## 3412. TERMINATION PROCEDURES FOR VIOLATIONS OF 42 CFR 489.24 AND/OR THE RELATED REQUIREMENTS AT 42 CFR 489.20(l), (m), (q), and (r)

A. Procedures for Termination When The Violation of 42 CFR 489.24 Is an Immediate and Serious Threat to Patient Health and Safety.--If the RO determines that an immediate and serious threat to patient health or safety exists, the termination procedures are completed within 23 calendar days. The processing time frames are the maximum allowed. The procedures are not postponed or stopped unless evidence of correction of the deficiencies or proof that the violation did not exist is obtained. The case is referred to the OIG which has responsibility for assessment of the CMPs against the hospital and/or physician and physician exclusion provisions for violations of 42 CFR 489.24. The case is also referred to the Office for Civil Rights (OCR) because OCR may take action under the Hill-Burton Subpart G Community Services regulations at 42 CFR 124.603(b)(1).

The 23-day termination procedure is as follows:

1. Day One.--This is the date on which the RO makes the determination of noncompliance with 42 CFR 489.24. It is the date of the preliminary determination letter. The preliminary determination letter informs the hospital:

- Of the RO's findings based on your investigation and the results of medical review, (if sought by the RO);

- Of the projected termination date (the 23rd day from the date of the preliminary determination letter);

- Of the date on which the RO will issue a Notice of Termination Letter and notify the public (at least two days, but no more than four days prior to the termination date); and

- That the hospital may avoid the termination action and notice to the public by either providing credible evidence of correction of the deficiencies or by successfully showing that the deficiencies did not exist.

In either case, the necessary information must be furnished to the HCFA RO in time for your office or the RO to have an opportunity to verify the corrections before the projected termination date.

2. Nineteenth Day.--The RO sends a Notice of Termination letter to the hospital and the State Medicaid agency if the hospital also participates in the Medicaid program. A public notice of the termination action is prepared.

3. Twenty-First Day.--The public notice is published.

NOTE: The RO notifies the public of the proposed termination action by the most expeditious means available. A newspaper notice or a press release to the radio and television stations serving the area are all appropriate options. The notice must be made at least two days, but no more than four days prior to the effective date of termination.

4. Twenty-Third Day.--Termination takes effect unless compliance has been achieved or threat has been removed.

The hospital has an opportunity to develop and implement a plan of corrective action. If the hospital alleges compliance or provides credible evidence that the immediate and serious threat to patient health and safety has been removed after initiation of termination action, the RO will direct you to resurvey. If that evidence is verified, the RO will switch from the 23-day termination procedures to the 90-day procedures. This allows the hospital time to prove that the corrective action is good for the long-term (i.e., the corrective action is adequate to ensure that no further violations will occur). The RO will direct you to perform a second resurvey within 60 days of the first. On the resurvey, examine emergency records for the period since the last survey to assess continued compliance.

The RO will send the complainant a letter reporting the final results of the investigation.

If the termination takes place and the hospital desires to become recertified as a Medicare provider, the hospital must provide reasonable assurance that compliance will be maintained. This means that sustained compliance must be demonstrated over a period of time, as determined by the HCFA RO. The hospital must have no cases of "dumping" for up to 30 days prior to the onsite survey in order to regain Medicare certification. Determine this through a rigorous review of emergency service records, as well as staff interviews during the onsite survey. When continued monitoring is appropriate to assure that corrective action has been taken, the RO will inform the provider of the period for which such monitoring will continue.

B. Procedures for Termination When The Violation of 42 CFR 489.24 and/or the Related Requirements of 42 CFR 489.20 Is Not Considered an Immediate and Serious Threat to Patient Health and Safety.--

1. Day One.--This is the date on which the RO makes the determination of noncompliance with 42 CFR 489.24 and/or the related requirements of 42 CFR 489.20. It is the date of the preliminary determination letter.

2. Day 70.--The RO sends a Notice of Termination letter to the hospital and a copy to the State Medicaid agency if the hospital also participates in the Medicaid program. The public notice of the termination action is prepared.

3. Day 75.--The public notice is published.

NOTE: The RO notifies the public of the proposed termination action by the most expeditious means available. A newspaper notice or a press release to the radio and television stations serving the area are all appropriate options. The notice must be made fifteen days prior to the effective date of termination.

4. Day 90.--Termination takes effect unless compliance has been achieved or threat has been removed.

## 3413. RO PROCEDURES FOR COORDINATING STATUTORILY MANDATED PRO REVIEW OF CONFIRMED DUMPING CASES

Before imposing sanctions under §1987(d) of the Act for violations of 42 CFR 489.24, and 42 CFR 489.24(g) requires that HCFA obtain consultation from the appropriate PRO. The OIG holds the authority to assess CMPs against the hospital or physicians or to exclude physicians from the Medicare program for violations of 42 CFR 489.24.

A. Procedures for Coordinating 60 day PRO Review--When the RO determines that a hospital was noncomplaint with the requirements of 42 CFR 489.24, one of its notice requirements is to notify the OIG that the violation was confirmed and that termination action has been initiated. (See Exhibit 208.) With the notification letter, the RO attaches a copy of the following:

- o Form HCFA-1541B;
- o Form HCFA-2567;
- o Medical record;
- o Summary of interviews;
- o Explanation of sample selection;
- o Copies of pertinent hospital policies and procedures related to the identified deficiencies;
- o Complaint investigation narrative;
- o Certification of benefits versus risks of the transfer (if this is a transfer case); and

o Copy of the 5-day advisory MR (if the RO had requested such a review to make its compliance determination).

The RO sends the above information, and any other pertinent documentation in its possession to the OIG at the following address:

Office for Civil Fraud and Administrative Adjudication
Office of Inspector General
U. S. Department of Health and Human Services
Room 5600 Cohen Building
330 Independence Avenue, S. W.
Washington, D. C. 20201

At the time of referral to the OIG, the RO asks the appropriate PRO (with a contract under Part B of title XI of the Act) to provide a medical opinion on the case and forwards the report to the OIG within 60 days. The RO uses the Model Letter Requesting PRO Review of a Confirmed Violation of 42 CFR 489.24 for Purposes of Assessing Civil Monetary Penalties or Excluding Physicians (Exhibit 212). The PRO will provide the physician and hospital reasonable notice of it review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. (Instructions on notice of review and opportunity for discussion, and additional information that follow the regulatory requirements in 42 CFR 489.24(g) are found in §§9100-9150 of the PRO Manual.)

The RO is responsible for providing the PRO with all information relevant to the case that is within its possession and control. The RO sends the Physician Review Outline for Emergency Care Obligations of Medicare Hospitals (Exhibit 138) to capture this information. This outline is helpful for organizing the review of the medical record. The specialty of the reviewing physician should be matched to the specialty of the physician who attended the patient and/or the individual's medical condition. If the patient was not seen by a physician, the RO uses the diagnosis of the patient or the usual physician assignment practice of the facility to determine the specialty of the physician reviewer.

Within 60 calendar days of receiving the case, the PRO must submit to the OIG a report on its findings and provide the RO with a copy of those findings. The report will provide an expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there are any medical utilization or quality of care issues involved in the case. The RO provides copies of the PRO report to the affected physician and/or hospital, if requested.

When there was no screening examination or when a delay would jeopardize the health or safety of individuals, PRO review is not required before the OIG may impose CMPs or exclude a physician from the Medicare program. In addition, if the PRO determines, after a preliminary review, that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, the PRO may, as its discretion, return the case to the RO with its opinion documented.

B. Releasing PRO Assessment--Upon request, the RO may release PRO assessment(s) to the physician and/or hospital or the affected individual, or his/her representative. The PRO physician's identity is confidential unless he/she consents to its release. PRO review may be released pursuant to the requirements of 42 CFR 476.132 and 476.133.